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HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
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OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

MEMORANDUM

Date: February 12, 2008

Subject: **Pyraclostrobin.** Petitions for the Establishment of Permanent Tolerances on: (i) Oat Grain, Hay, and Straw, and Oilseeds (Rapeseed Subgroup) - PP#6E7105; (ii) Fresh Herbs (Herbs Subgroup 19A), Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple - PP#6E7165; and (iii) Barley Grain and Straw- PP#7E7245. Summary of Analytical Chemistry and Residue Data.

DP Barcodes:	343754, 344624, 344625, 345965, and 348700	Decision Numbers:	381720, 370226, and 373145
PC Code:	099100	MRID Nos.:	47014801 through 47014804, 46925301, 46902226, and 47190501
40 CFR §180.	582		
Chemical Class:	Strobilurins		

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This document was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Durham, NC 27713; submitted 10/31/2007). The document has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

Executive Summary

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination, mycelial growth, and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit, and nut crops. It is formulated as water-dispersible granules (WDG) or an emulsifiable concentrate (EC) and is typically applied as foliar applications using ground or aerial equipment at maximum seasonal rates of 0.3-3.0 lb ai/A. The 20% WDG formulation is also registered for use as a seed treatment on some crops.

Pyraclostrobin tolerances have been established in 40 CFR §180.582. Tolerances for plant commodities are listed in 40 CFR §180.582 (a)(1) and are expressed in terms of the combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate), expressed as parent compound. The established tolerances for plant commodities range from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*.

Tolerances for animal commodities are listed in 40 CFR §180.582 (a)(2) and are expressed in terms of the combined residues of the fungicide pyraclostrobin and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound. The established tolerances for livestock commodities range from 0.1 to 1.5 ppm; no tolerances are established for poultry commodities.

In PP#6E7105, BASF requests the establishment of tolerances for the combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl-N-[[[1-(4-chlorophenyl)pyrazol-3-yl]oxy]-o-tolyl] carbamate), expressed as parent compound, in/on the following commodities:

Oats grain ..... 1.0 ppm

Oats, hay.....17 ppm
Oats, straw.....17 ppm
Oilseed, group 20.....0.4 ppm

Concurrently, BASF wishes to amend the product label for Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin, to add new foliar uses on oats, canola, and flax. Headline® Fungicide is proposed for foliar applications at maximum seasonal rates of 0.39 lb ai/A for canola and flax and 0.29 lb ai/A for oats. Applications may be made using ground or aerial equipment. The proposed preharvest intervals (PHI) range from 21 days (oilseed crops) to the beginning of flowering stage (oats). In addition, the petitioner wishes to register BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation, for seed treatment on oats, canola, and flax. BAS 500 ST is proposed for seed treatment at maximum rates of 0.005-0.04 lb ai/100 lb seed.

In PP#6E7165, IR-4 requests the establishment of pyraclostrobin tolerances, expressed as parent *per se*, in/on the following commodities:

Herb subgroup 19A, fresh herb.....30.0 ppm
Avocado.....0.7 ppm
Sapote, black.....0.7 ppm
Canistel.....0.7 ppm
Sapote, mamey.....0.7 ppm
Mango.....0.7 ppm
Papaya.....0.7 ppm
Sapodilla.....0.7 ppm
Star Apple.....0.7 ppm

[* It is noted that pyraclostrobin tolerances are established for mango and papaya at 0.1 ppm each. However, there are currently no U.S. registrations on mango and papaya as of 02/11/2008.]

Concurrent with the tolerances proposed above, IR-4 wishes to amend the product label for Pristine® Fungicide (EPA Reg. No. 7969-199) to incorporate new uses on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs. Pristine® Fungicide is a WDG formulation containing multiple active ingredients of pyraclostrobin (12.8%) and boscalid (25.2%). The product is proposed for two foliar applications on the above crops at a maximum seasonal rate of 0.3 lb ai/A with a 0-day PHI for pyraclostrobin.

Under PP#7E7245, IR-4 requests the establishment of tolerances for the combined residues of the fungicide pyraclostrobin and its desmethoxy metabolite, expressed as parent compound, in/on the following commodities:

Barley, grain.....1.3 ppm
Barley, straw.....9.0 ppm

Concurrently, IR-4 wishes to amend the product label for Headline® Fungicide (EPA Reg. No. 7969-186) to revise the barley PHI from "apply no later than 50% head emergence (Feekes 10.3, Zadok's 55)" to 14 days. The maximum seasonal rate of 0.29 lb ai/A remains the same.

The nature of the residue in plants, rotational crops, and animals is adequately understood. In *plants*, the results of metabolism studies conducted on grape, potato and wheat indicate that pyraclostrobin and its desmethoxy metabolite (BF 500-3) are the major residues in crop matrices including livestock feeds; tryptophan was found to be the major residue in potato tuber and wheat grain when carbon-14 was introduced in the tolyl ring (*via* the shikimic acid pathway). The major degradation reactions are the removal of the methoxy group from the carbamate nitrogen and breakage of the ether bond. In *rotational crops*, it was shown that pyraclostrobin and its desmethoxy metabolite are the major residues taken up into the plants. In the *goat*, the major residues are pyraclostrobin and BF 500-3 in muscle and fat; pyraclostrobin, BF 500-3, and BF 500-5 (1-(4-chlorophenyl)-1*H*-pyrazol-3-ol) and its sulfate conjugate in milk; pyraclostrobin, BF 500-3, and BF 500-5 and its sulfate conjugate, and hydroxylated desmethoxy metabolite (500M67) in kidney; and metabolites hydrolyzed to BF 500-5 and its hydroxylated compound (BF 500-8 (1-(4-chloro-2-hydroxyphenyl)-1*H*-pyrazol-3-ol) in liver. In *poultry*, the major residues are pyraclostrobin and BF 500-3 in eggs; pyraclostrobin, BF 500-3, and hydroxylated BF 500-3 (500M64) in fat; the glucuronic acid conjugate of hydroxylated BF 500-3 (500M32) in liver. Radioactive residues were below detection in muscle. The main degradation reactions in livestock consist of demethoxylation, hydroxylation, and conjugation, and breaking of the ether bond.

The HED Metabolism Assessment Review Committee (MARC memo of 10/9/01, DP# 278044, L. Cheng) has determined that for purposes of tolerance and dietary risk assessments, the residues of concern in plant and rotational crop commodities include pyraclostrobin and metabolite BF 500-3. The residues of concern in livestock commodities include pyraclostrobin and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol (BF 500-5) and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol (BF 500-8).

There are adequate residue analytical methods for tolerance enforcement and data collection. The analytical methods (LC/MS/MS and HPLC/UV) for plant commodities measure pyraclostrobin and its desmethoxy metabolite. The methods (GC/MS and LC/MS/MS) for livestock commodities convert pyraclostrobin and related metabolites to chlorophenylpyrazolol (BF 500-5) and hydroxylated chlorophenylpyrazolol (BF 500-8) in goats and chlorophenylpyrazolol (BF 500-5) and hydroxylated chlorophenylpyrazolol (BF 500-9) in poultry. These methods were successfully validated by an independent laboratory and validated using radiolabeled samples from metabolism studies. The proposed enforcement methods have been forwarded to ACB/BEAD for petition method validations. Samples of raw agricultural and processed commodities from the current petitions were analyzed for pyraclostrobin residues of concern using an adequate LC/MS/MS method (BASF Method D9908), which is similar to the proposed enforcement method. The method was adequately validated in conjunction with the field trial analyses. For each analyte, the validated limit of quantitation (LOQ) is 0.02 ppm, and the estimated limits of detection (LODs) are 0.003-0.03 ppm.

The requirements for multiresidue methods testing data are fulfilled. Pyraclostrobin was successfully evaluated through several of the FDA protocols (complete recovery through protocols D and E), while recovery of metabolite BF 500-3 was unsuccessful in all protocols.

There are adequate storage stability data from previous pyraclostrobin petition submissions. These data may be translated in the current petition to validate sample storage conditions and durations. There are no corrections which need to be applied as pyraclostrobin residues of concern were found to be reasonably stable over a wide range of commodities under frozen storage conditions for 19-25 months.

Adequate cattle and poultry feeding studies are available to support the livestock dietary burdens resulting from the proposed uses. Dietary burdens were calculated for beef (4.7 ppm), dairy (8.8 ppm), poultry (1.0 ppm), and swine (0.2 ppm). The calculations reflect the most recent guidance from HED concerning revisions of feedstuff percentages in Table 1 and constructing reasonably balanced livestock diets. Based on these dietary exposure levels and the residue data from the ruminant feeding study, the existing pyraclostrobin tolerances for milk, meat, fat, meat byproducts except liver, and liver of cattle, goats, hogs, horses, and sheep are adequate, and no adjustments are needed. Tolerances for eggs and poultry are not needed at this time based on data from the poultry feeding and metabolism studies [Category 180.6(a)(3)]. If in the future, the petitioner proposes a use which increases the dietary burdens of poultry, then the Category 3 situation will be re-evaluated.

The submitted field trial data for canola seed are adequate. Although adequate residue data have been submitted and a tolerance has been established for sunflower seed, the other representative member of the new proposed Oilseed Crop Group 20, a crop group tolerance will not be appropriate at this time until the Federal Register is issued revising the Crop Group Regulation to establish the Oilseed Crop Group 20; see 6/14/06 memo by B. Schneider entitled "Reviewer's Guide and Summary of HED ChemSAC Approvals for Amending Crop Groups/Subgroups [40 CFR §180.41] and Commodity Definitions [40 CFR §180.1(h)]. In the interim, tolerances for the representative commodities as well as all members of the crop group for which uses are being proposed will be listed individually.

The submitted field trial data for oat grain, straw, and hay are adequate pending label revision to specify appropriate PHIs and tolerance adjustment. The petitioner did not provide residue data or propose a tolerance for oat forage because per the proposed label directions, applications are made after the growth stages at which oat is foraged.

The submitted field trial data for basil (fresh and dried) and chives, the representative commodities of Herbs subgroup 19A, along with those data submitted for dill (fresh and seed) are inadequate because the trials were conducted at an exaggerated rate (2.7x the maximum proposed seasonal rate). Thus the submitted data represent an overestimate of the residues expected from the proposed use. Given that the proposed use is for late season foliar application, and includes a 0-day preharvest interval, HED will use the submitted data to support a tolerance for the Herbs subgroup 19A.

The submitted residue data for avocado are inadequate to fulfill data requirements because the field trials were conducted at exaggerated rates (ca 2.6x). Thus the submitted data represent an overestimate of the residues expected from the proposed use. Given that the proposed use is for late season foliar application, and includes a 0-day preharvest interval, HED will use the submitted data to support a tolerance for avocado. The avocado data may be translated to other tropical fruits for which uses are proposed. HED is in the process of revising the Commodity

Definitions listed under 40 CFR §180.1(h) to make the tropical/subtropical fruit avocado a general commodity; see same 6/14/06 memo by B. Schneider. The specific commodities included in the general definition for avocado include black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple. Until the regulations have been finalized in the Federal Register, separate tolerances are needed for each specific commodity, at the same level as the respective general commodity tolerance. However, since HED believes that the tropical fruit tolerances may need to be reduced; and further, since the avocado data are being translated to support a wide number of tropical/subtropical fruits, HED requests that the petitioner provide additional bridging data. HED recommends the conduct of two to three avocado field trials at the proposed label rate as a condition of registration.

The submitted field trial data for barley grain and straw are adequate pending tolerance adjustment. No residue data were submitted for barley hay, and normally these data are required to support the amended use pattern. However, the petitioner did not provide residue data or propose a tolerance for barley hay because per the propose label directions, applications are made after the growth stages at which barley hay is harvested. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for barley hay.

Acceptable processing studies on basil and canola were submitted. Barley and oat processing data were not submitted and are normally required to support the proposed use of pyraclostrobin on barley and oats. However, data from the wheat processing studies (MRID #'s 45118620 and 45321101) can be translated to adequately support the proposed uses on barley and oats. Based on the wheat studies, residues are not expected to concentrate in barley or oat processed commodities.

The processing of fresh basil to dried basil resulted in an increase of total pyraclostrobin residues with an observed processing factor range of 4.6-9.0x for dried basil leaves. A tolerance for dried basil most be proposed. In addition, a tolerance must be proposed for dill seed. The canola processing study indicates that total residues concentrated marginally in refined oil (1.2x) but reduced in meal (0.8x). No tolerances are needed for canola processed products.

An acceptable limited field rotational crop study has been submitted and reviewed. Based on the available data, the petitioner needs to submit a revised Section B to specify a 14-day plantback interval restriction for all annual crops that are not registered.

There are no Canadian or Mexican MRLs for pyraclostrobin for the crop commodities discussed in this Summary Document. There are Codex MRLs established at 0.5 ppm for oats and at 0.05 ppm for papaya. The US tolerance level and residue definition both differ from Codex because of label rates.

Analytical reference standards for pyraclostrobin and its regulated metabolites are available at the EPA National Pesticide Standards Repository

Regulatory Recommendations and Residue Chemistry Deficiencies

PP#6E7105

Pending resolution of deficiencies for oats (label revision to specify appropriate rotational plantback interval (see requirements under 860.1900 Field Accumulation in Rotational Crops), and the submission of a revised Section F (see requirements under 860.1550 Proposed Tolerances), there are no residue chemistry issues that would preclude granting a conditional registration for the requested uses of pyraclostrobin on oats, canola, and flax. Registration should be made conditional pending resolution of the data gaps cited above. The proposed uses and the submitted and/or translated data support the following tolerances for residues of pyraclostrobin residues of concern in/on the following raw agricultural commodities. In addition, in the interim of final published rule for formation of "Oilseed Crop Group 20", tolerances are recommended for all remaining oilseeds to be listed in the rapeseed, sunflower, and cotton subgroups.

Oat, grain.....1.0 ppm
Oat, hay.....18 ppm
Oat, straw.....15 ppm

Borage, Crambe, Cuphea, Echium, Flax seed, Gold of pleasure, Hare's ear mustard, Lesquerella, Lunaria, Meadowfoam, Milkweed, Mustard seed, Oil radish, Poppy seed, Rapeseed, Sesame, Sweet rocket (rapeseed subgroup);

Castor oil plant, Chinese tallowtree, Euphorbia, Evening primrose, Jojoba, Niger seed, Rose hip, Safflower, Stokes aster, Sunflower, Tallowwood, Tea oil plant, Vernonia (sunflower subgroup);

Cotton (cotton subgroup).....0.45 ppm

860.1500 Crop Field Trials

Oats: No residue data are submitted for oat forage. The petitioner did not provide residue data or propose a tolerance for oat forage because per the proposed label directions, applications are made after the growth stages at which oat is foraged. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for oat forage.

860.1900 Field Accumulation in Rotational Crops

Label revisions are required to specify a 14-day plantback interval restriction for all annual crops that are not registered.

860.1550 Proposed Tolerances

The petitioner must submit a revised Section F reflecting the recommended tolerances and commodity definitions presented in Table 16.

860.1520 Processed Food and Feed

Oats: No residue data for the oat processed commodities (flour and groats/rolled oats) are submitted. However, data from the wheat processing studies (MRID #'s 45118620 and 45321101) can be translated to adequately support the proposed use on oat. Based on the wheat studies, residues are not expected to concentrate in oat processed commodities.

Barley: No residue data for the barley processed commodities (bran and pearled) are submitted. However, data from the wheat processing studies (MRID #'s 45118620 and 45321101) can be translated to adequately support the proposed use on barley. Based on the wheat studies, residues are not expected to concentrate in barley processed commodities.

PP#6E7165

Pending resolution of deficiencies for Herbs subgroup 19A and avocados (see requirements under 860.1200 Directions For Use and 860.1500 Crop Field Trials), label revision to specify appropriate rotational plantback interval (see requirements under 860.1900 Field Accumulation in Rotational Crops), and the submission of a revised Section F (see requirements under 860.1550 Proposed Tolerances), there are no residue chemistry issues that would preclude granting permanent tolerances and a conditional registration for the requested uses of pyraclostrobin on Herbs subgroup 19A, avocados, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple. Registration should be made conditional pending resolution of the data gaps cited above. The proposed uses and the submitted and/or translated data support the following tolerances for residues of pyraclostrobin residues of concern in/on the following subgroup and raw agricultural commodities:

Herbs subgroup 19A	25.0 ppm
Avocado	0.6 ppm
Sapote, black	0.6 ppm
Canistel	0.6 ppm
Sapote, mamey	0.6 ppm
Mango	0.6 ppm
Papaya	0.6 ppm
Sapodilla	0.6 ppm
Star Apple	0.6 ppm
Basil, dried leaves	85 ppm
Dill seed	25 ppm

860.1200 Directions For Use

Herbs subgroup 19A: The petitioner has submitted a product label for Pristine® Fungicide. According to the proposed label directions "Do not apply more than 37 oz/A per season" (which equals 0.3 lb pyraclostrobin), this application rate was exceeded in the field trials. Based on the submitted data, four foliar applications at ca. 0.2 lb ai/A/application, with retreatment intervals of 6-8 days, for a seasonal rate of 0.8 lb ai/A with a 0-day PHI was applied. HED usually allows a revised Section B to reflect this different rate used in the field trials.

However, the proposed formulation contains two active ingredients, i.e., pyraclostrobin (12.8%) and boscalid (25.2%). A review of the boscalid data (See memo of 11/27/2007, C. Olinger), shows that boscalid was applied only twice but by using a different formulation, for a total of 0.59 lb a.i./A. This matches the proposed use rate for boscalid. If applied at the proposed label rate for pyraclostrobin (2 applications/season, 0.3 lb ai/A/season), then boscalid would be applied at the proposed rate (2 applications/season, 0.58 lb ai/A/season). However, if this formulation is applied at the exaggerated rate as representative of the submitted field trials, pyraclostrobin would be applied at 0.8 lb/ai/A/season, while boscalid would be applied at 1.58 lb ai/A/season (2,7x). Although the recommended pyraclostrobin tolerance would cover any pyraclostrobin residues at 4 applications/season, boscalid residues at this treatment rate would probably exceed the recommended tolerance for boscalid. Thus, if it is the intent of the petitioner to propose this combined formulation for herbs (subgroup 19A), then a simple label revision will not solve the problem. The data only support 2 applications. The proposed label cannot be revised to match the submitted pyraclostrobin residue field trial data.

860.1500 Crop Field Trials

Herbs subgroup 19A: HED will allow these data to support the proposed use on herbs. However, HED believes that the recommended tolerance (based on 4 applications/season) would be higher than needed to cover pyraclostrobin residues that might exist on herbs treated at the proposed label rate (2 applications/season).

Avocado: A similar problem has been noted with the field trial data for avocado because exaggerated rates were used. To resolve these data gathered at exaggerated rates, HED has requested additional bridging field trial data at the label maximum rate (2 applications, total 0.3 lb ai/season) for pyraclostrobin on avocado (See this memo).

860.1900 Field Accumulation in Rotational Crops

Label revisions are required to specify a 14-day plantback interval restriction for all annual crops that are not registered.

860.1550 Proposed Tolerances

The petitioner should submit a revised Section F to correct the tolerance residue definition (parent + metabolite) and to make it consistent with the definition listed in 40 CFR §180.582 (a)(1). The revised Section F should also incorporate the recommended tolerances and commodity definitions presented in Table 16.

A human health risk assessment is forthcoming.

PP#7E7245

Pending submission of residue data for barley forage (label revision to specify appropriate rotational plantback interval (see requirements under 860.1900 Field Accumulation in Rotational Crops), and the submission of a revised Section F (see requirements under 860.1550 Proposed Tolerances), there are no residue chemistry issues that would preclude granting the requested

amended use pattern for barley. The proposed uses and the submitted data support the following tolerances for residues of pyraclostrobin residues of concern in/on the following raw agricultural commodities:

Barley, grain ..... 1.4 ppm
Barley, straw ..... 6.0 ppm

860.1500 Crop Field Trials

Barley. No residue data were submitted for barley forage, and these data are normally required to support the amended use pattern. However, the petitioner did not provide residue data or propose a tolerance for barley hay because per the proposed label directions, applications are made after the growth stages at which barley hay is harvested. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for barley hay.

860.1520 Processed Food and Feed

Barley: Residue data for the barley processed commodities (pearled barley and bran) are normally required. However, data from the wheat processing studies (MRID #'s 45118620 and 45321101) can be translated to adequately support the proposed use on barley. Based on the wheat studies, residues are not expected to concentrate in barley processed commodities.

860.1900 Field Accumulation in Rotational Crops

Label revisions are required to specify a 14-day plantback interval restriction for all annual crops that are not registered.

860.1550 Proposed Tolerances

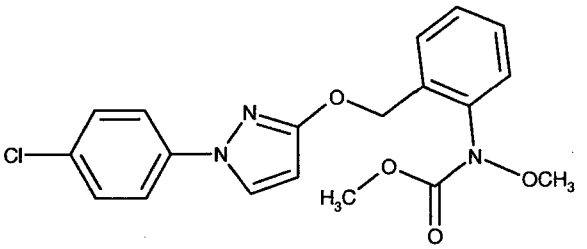
The petitioner should submit a revised Section F reflecting the recommended tolerances and commodity definitions presented in Table 16.

A human health risk assessment is forthcoming.

Background

The chemical structure and nomenclature of pyraclostrobin are presented in Table 1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table 2.

Table 1. Pyraclostrobin Nomenclature.

Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use products (EP)	2 lb/gal EC (Headline® Fungicide; EPA Reg. No. 7969-186) 20% WDG (Cabrio® Fungicide; EPA Reg. No. 7969-187) 12.8% WDG (Pristine® Fungicide; EPA Reg. No. 7969-199) [1]

[1] This formulation is a MAI which also contains 25.2% of boscalid.

TABLE 2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

860.1200 Directions for Use

A summary of the pyraclostrobin end-use products proposed for use on the crops discussed in this document is listed in Table 3. Table 4 presents the summary of proposed crop use patterns. No rotational crop restrictions are listed on the product labels.

Table 3. Summary of Proposed Pyraclostrobin End-Use Products.

Trade Name	Reg. No.	% ai of formulation	Formulation Type	Target Crops	Label Date
Headline® Fungicide	7969-186	23.6, (2.09 lb ai/gal)	EC	Canola, flax, barley, and oats	Undated label attached in Section B
BAS 500 ST	7969-EUN	20	WDG	Oats and oilseed crops	Undated label attached in Section B
Pristine® Fungicide	7969-199	12.8	WDG	Avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs	Undated label attached in Section B

Table 4. Summary of Directions for Use of Pyraclostrobin.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Fresh Herbs (including Angelica, Balm, Basil, Borage, Burnet, Chamomile, Catnip, Chervil, Chive, Chinese Chive, Clary, Coriander (leaf), Costmary, Cilantro (leaf), Curry (leaf), Dillweed (fresh and for processing into oil), Horehound, Hyssop, Lavender, Lemongrass, Lovage (leaf), Marigold, Marjoram (*Origanum* spp.), Nasturtium, Parsley, Pennyroyal, Rosemary, Rue, Sage, Summer Savory, Winter Savory, Sweet Bay, Tansy, Tarragon, Thyme, Wintergreen, Woodruff, and Wormwood)						
Foliar Ground, aerial or through sprinkler irrigation	12.8% WDG [7969-199]	0.15	2	0.30	0	Begin applications prior to the onset of disease development and repeat applications 7 days later as needed, or alternate with another registered fungicide having a different mode of action.
Avocado, Black Sapote, Canistel, Mamey Sapote, Mango, Papaya, Sapodilla, and Star Apple						
Foliar Ground, aerial or through sprinkler irrigation	12.8% WDG [7969-199]	0.15	2	0.30	0	Begin application prior to the onset of disease development and repeat applications 7 days later as needed, or alternate with another registered fungicide having a different mode of action.
Canola and Flax						
Foliar Ground, aerial or through sprinkler irrigation	23.6% EC (2.09 lb/gal) [7969-186]	0.10	Not specified	0.39	21	Begin applications prior to disease development, and continue on a 7- to 14-day interval if conditions are conducive for disease development. To limit the potential for development of resistance, do not make more than one application before alternating to a fungicide with a different mode of action. May be used with adjuvants.
Seed treatment	20% WDG [7969-EUN]	0.02-0.04 lb ai/100 lb of seed	1	0.02-0.04 lb ai/100 lb of seed	N/A	For control of seed and seedling disease caused by *Pythium* spp. on black mustard, crambe, field mustard, flax, Indian mustard, Indian rapeseed, rapeseed (canola), safflower, and sunflower, apply only in conjunction with registered rates of mefenoxam- or metalaxyl-containing seed treatment products.

Table 4. Summary of Directions for Use of Pyraclostrobin.

Applic. Timing, Type, and Equip.	Formulation [EPA Reg. No.]	Applic. Rate (lb ai/A)	Max. No. Applic. per Season	Max. Seasonal Applic. Rate (lb ai/A)	PHI (days)	Use Directions and Limitations
Oats						
Foliar Ground, aerial or through sprinkler irrigation	23.6% EC (2.09 lb/gal) [7969-186]	0.15	2	0.29	14 (hay or feed green-chopped oats)	Begin applications prior to disease development, immediately after flag leaf emergence. Apply no later than the beginning of flowering (Feeke's 10.5.to Zadok's 59) stage. May be used with adjuvants.
Seed treatment	20% WDG [7969-EUN]	0.005-0.01 lb ai/100 lb of seed	1	0.005-0.01 lb ai/100 lb of seed	N/A	
Barley						
Foliar Ground, aerial or through sprinkler irrigation	23.6% EC (2.09 lb/gal) [7969-186]	0.15	2	0.29	14 (hay or feed green-chopped barley)	Use limited to the following states: AZ, CO, ID, MT, NV, NM, OR, TX, UT, WA, and WY. Begin applications prior to disease development, immediately after flag leaf emergence. Apply no later than 50% head emergence (Feeke's 10.3.to Zadok's 55) stage. May be used with adjuvants.

Conclusions. The field trial data for some crops do not reflect the proposed use pattern since they were conducted at exaggerated rates. Additional bridging field trial residue data are required to reflect the proposed label rates for avacado. In addition, label revision is required to specify appropriate rotational crop restrictions. Details of label revisions are incorporated in the respective crop section.

860.1300 Nature of the Residue - Plants

HED Metabolism Assessment Review Committee Decision Memo, DP# 278044, 10/9/01, L. Cheng Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

The nature of the residue in plants is adequately understood based on acceptable metabolism studies conducted on grape, potato, and wheat. The metabolism of pyraclostrobin is similar in the three crops investigated. Pyraclostrobin and its desmethoxy metabolite (BF 500-3) are the major residues in crop matrices including livestock feeds; tryptophan was found to be the major residue in potato tuber and wheat grain when carbon-14 was introduced in the tolyl ring (*via* the shikimic acid pathway). The major degradation reactions are the removal of the methoxy group from the carbamate nitrogen and breakage of the ether bond.

The HED MARC has determined that for the purpose of tolerance and risk assessment, the terminal residues of concern in plants consist of pyraclostrobin and its metabolite BF 500-3.

860.1300 Nature of the Residue - Livestock

HED Metabolism Assessment Review Committee Decision Memo, DP# 278044, 10/9/01, L. Cheng Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

The nature of the residue in livestock is adequately understood based on acceptable ruminant and poultry metabolism studies. In the *goat*, the major residues are pyraclostrobin and BF 500-3 in muscle and fat; pyraclostrobin, BF 500-3, and BF 500-5 and its sulfate conjugate in milk; pyraclostrobin, BF 500-3, and BF 500-5 and its sulfate conjugate, and hydroxylated desmethoxy metabolite (500M67) in kidney; and metabolites hydrolyzed to BF 500-5 and its hydroxylated compound (BF 500-8) in liver. In *poultry*, the major residues are pyraclostrobin and BF 500-3 in eggs; pyraclostrobin, BF 500-3, and hydroxylated BF 500-3 (500M64) in fat; the glucuronic acid conjugate of hydroxylated BF 500-3 (500M32) in liver. Radioactive residues were below detection in muscle. The main degradation reactions in livestock consist of demethoxylation, hydroxylation, and conjugation, and breaking of the ether bond.

The HED MARC has determined that for the purpose of tolerance and risk assessment, the residues of concern in livestock commodities consist of pyraclostrobin and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol (BF 500-5) and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol (BF 500-8).

860.1340 Residue Analytical Methods

Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)
Residue Chemistry Memo DP# 269850, 11/8/00, L. Cheng (PP#0F6139)

There are adequate residue analytical methods for tolerance enforcement and data collection.

Plant commodities. Two adequate methods were proposed in PP#0F6139 for enforcing tolerances for residues of pyraclostrobin and the metabolite BF 500-3 in/on plant commodities: an LC/MS/MS method (BASF Method D9808) and an HPLC/UV method (Method D9904). The validated method LOQ for both pyraclostrobin and BF 500-3 is 0.02 ppm in all tested plant matrices, for a combined LOQ of 0.04 ppm. Adequate independent method validation and radiovalidation data had been submitted for both methods and forwarded to ACB/BEAD for a petition method validation.

Samples of raw agricultural and processed commodities from the current petitions were analyzed for residues of pyraclostrobin and its desmethoxy metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500-3 are expressed as pyraclostrobin equivalents. For each analyte, the validated method LOQ is 0.02 ppm, and the estimated LODs are 0.003-0.03 ppm. The method is adequate for data collection based on acceptable concurrent method recovery data.

Animal commodities: In the previous petition, PP#0F06139, two tolerance enforcement methods were proposed for ruminant commodities: HPLC/UV method 439/0 and Method 446, consisting of GC/MS method 446/0 and LC/MS/MS method 446/1. The HPLC/UV method determines residues of pyraclostrobin *per se*. Method 446 has a hydrolysis step, and determines residues of pyraclostrobin and its metabolites as BF 500-5 and BF 500-8. The validated method

LOQs for BF 500-5 type residues, in parent equivalents, are 0.01 ppm for milk and 0.05 ppm for tissues, and the validated LOQs for BF 500-8 type residues, in parent equivalents, are 0.01 ppm for milk and 0.05 ppm for tissues. Independent method validation data for the HPLC/UV and LC/MS/MS methods are acceptable. Radiovalidation data submitted for the GC/MS and LC/MS/MS methods are adequate for liver and milk, and marginal for muscle. Method 446 has been forwarded to ACB/BEAD for petition method validation. The petitioner had been requested to modify the proposed enforcement method to include any modifications made by the EPA laboratory during the Agency laboratory validation. An enforcement method for poultry was reviewed in PP#0F06139. However, tolerances for poultry egg and tissues have not been established and are not required for the purpose of these petitions.

860.1360 Multiresidue Methods

Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

A cursory summary of the multiresidue methods testing data for pyraclostrobin and its metabolite BF500-3 was reported in PP#0F6139. Pyraclostrobin was successfully evaluated through several of the FDA protocols, while recovery of BF 500-3 was unsuccessful in all protocols. Pyraclostrobin was completely recovered through Protocol D (in grape) and E (in grape), and partially recovered through Protocol F (in peanut). Metabolite BF 500-3 had poor peak shape and inadequate sensitivity with Protocol C columns, and therefore, was not further analyzed under Protocol D, E, and F. The results of the multiresidue testing for pyraclostrobin were forwarded to FDA on 1/4/02 for the purpose of updating PAM, Volume I.

860.1380 Storage Stability

Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

Adequate storage stability data are available indicating that pyraclostrobin and metabolite BF 500-3 are reasonably stable at ≤-10 °C in fortified samples of grape juice (juices), sugar beet tops (leafy vegetables), sugar beet roots (root crop), tomatoes (fruit/fruiting vegetable), and wheat grain (non-oily grain) and wheat straw (dry feed) for up to 25 months, and in fortified samples of peanut nutmeats (oilseed) and peanut oil for up to 19 months.

The storage intervals and conditions for samples collected from the magnitude of the residue and processing studies discussed in this Summary Document are presented below in Table 5.

Table 5. Summary of Storage Conditions and Intervals of Samples from Crop Field Trials.

Matrix	MRID	Storage Temperature (°C)	Actual Storage Duration (Months)	Interval of Demonstrated Storage Stability (months)
Fresh dill	47014801	-10	5.7	19
Dill seed			4.9	
Chives	47014802	-10	3.8	19
Fresh basil	47014803	-10	5.7	19
Dried basil			5.4	
Avocado	47014804	-10	6.1	19
Canola seed	46925301	-10	5.8-7.6	19
Processed canola seed			3.3	
Canola meal			2.5	
Refined canola oil			1.8	

Table 5. Summary of Storage Conditions and Intervals of Samples from Crop Field Trials.				
Matrix	MRID	Storage Temperature (°C)	Actual Storage Duration (Months)	Interval of Demonstrated Storage Stability (months)
Oat hay	46902226	-10	7.6-12.4	19-25
Oat grain			7.2-11.3	
Oat straw			7.0-11.4	

Conclusions. There are adequate storage stability data from PP#0F6139 which may be translated in the current petition to validate sample storage conditions and durations. There are no corrections which need to be applied as pyraclostrobin residues of concern were found to be relatively stable over a wide range of commodities under frozen storage conditions for 19-25 months.

860.1400 Water, Fish, and Irrigated Crops

This guideline requirement is not relevant to the current petitions as there are no aquatic uses being proposed for pyraclostrobin.

860.1460 Food Handling

This guideline requirement is not relevant to the current petitions as there are no food-handling uses being proposed for pyraclostrobin.

860.1480 Meat, Milk, Poultry, and Eggs

Livestock dietary burdens

The potential for secondary transfer of pyraclostrobin residues of concern in meat, milk, poultry, and eggs exists because there are several livestock feedstuffs (canola meal, oat grain, oat forage, oat straw, and oat hay) that are associated with the proposed uses in the current petitions. The livestock dietary burdens of pyraclostrobin are presented in Table 6, and reflect the most recent guidance from HED concerning revisions of feedstuff percentages in Table 1 and constructing reasonably balanced livestock diets (RBDs). The calculated dietary burdens of pyraclostrobin are estimated at 4.7 ppm for beef, 8.9 ppm for dairy, 1.0 ppm for poultry, and 0.2 ppm for swine.

Table 5. Calculation of Reasonably Balanced Dietary Burdens (RBDBs) of Pyraclostrobin Residues for Livestock. [1]

Feedstuff	Type	% Dry Matter	% Diet	Tolerance (ppm)	Dietary Contribution (ppm)
Beef Cattle R 15%, CC 75%, PC 10%					
Barley, hay/(oat, hay)	R	88	10	25(18)	2.84
Cotton, gin byproducts	R	90	5	30	1.7
Barley, grain	CC	88	20	0.4	0.09
Corn, field, grain/milled byproducts	CC	88	55	0.1	0.063
Canola/sunflower, meal	PC	92	10	0.3	0.03
TOTAL BURDEN	--	--	100	--	**4.72 (4.7)**
Dairy Cattle R 45%, CC 45%, PC 10%					
Almond, hulls	R	90	5	1.6	0.09
Corn, field, forage (silage)	R	40	35	5.0	4.38
Legume, hay (cowpea)	R	30	5	25	4.17
Barley, grain	CC	88	20	0.4	0.09
Corn, field, grain/milled byproducts	CC	88	25	0.1	0.03
Cotton, undelinted seed	PC	90	10	0.3	0.03
TOTAL BURDEN	--	--	100	--	**8.79 (8.8)**
Poultry CC 75-80%, PC 20-25%					
Barley, grain	CC	88	10	0.4	0.04
Oat, grain	CC	88	70	1.2	0.84
Canola/sunflower, meal	PC	92	20	0.3	0.06
TOTAL BURDEN	--	--	100	--	**0.94 (1.0)**
Swine CC 80-85%, PC 15-20%					
Barley, grain	CC	88	20	0.4	0.08
Corn, field, grain	CC	88	65	0.1	0.065
Canola/sunflower, meal	PC	92	15	0.3	0.045
TOTAL BURDEN	--	--	100	--	**0.19 (0.2)**

[1] All data are based on Table 1 Feedstuffs (October 2006), a revision of feedstuffs data found in Table 1 (180.1000 OPPTS Test Guidelines). Residue levels for beef and dairy are corrected for moisture content and are determined by formula: tolerance / %DM x % in diet. Residue levels for poultry and swine are considered "as-is" and are determined by formula: tolerance x % in diet. R: roughage; CC: carbohydrate concentrate; PC: protein concentrate.

Typical compositions of daily rations for the animals of choice for Table 1 data follow:

Feedlot beef are fed higher amounts of CC (up to 80 %), and lower amounts of R (15-20 %) and PC (5-10 %) as the slaughter time (last 3 months) gets closer. High volume milk-producing lactating dairy cows have a daily ration of 45 % R, 40-45 % CC, and 10-15 % PC.
A laying hen that will give a steady egg production is fed 75-80 % CC and 20-25 % PC. A marketable hog diet that will give steady growth would have 80-85 % CC and 15-20 % PC.

Animal feeding studies: Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

Adequate feeding studies were reviewed in PP#0F6139. The current pyraclostrobin tolerances for livestock commodities were established based on results from these studies and the Agency's estimated dietary burdens for pyraclostrobin residues, which were originally calculated to be 36.3 ppm for beef cattle, 35.4 ppm for dairy cattle, and 0.35 ppm for poultry. The more recent dietary burden for pyraclostrobin residues are estimated at 4.7 ppm (beef), 8.8 ppm (dairy), 1.0 ppm (poultry), and 0.2 ppm (swine). Thus using these revised estimates in the ruminant feeding study, dairy cows were dosed orally for 28 days with pyraclostrobin at levels equivalent to 8.8 ppm (1x the recalculated dietary burden), 27.2 ppm (3x), and 89.6 ppm (10x) in their diet. The study results from the 27.2 ppm-dose level were reproduced from the initial petition review and are presented in below Table 7.

Table 7. Residues of pyraclostrobin and its metabolites hydrolyzable to BF 500-5 and BF 500-8 in milk and tissues from cows dosed twice daily with pyraclostrobin at levels equivalent to 27.2 ppm for 28 consecutive days.

Dosing or Sampling Day	Mid Dose (27.2 ppm)			
	HPLC/UV Method 439	GC/MS (milk) Method 446/0 or LC/MS/MS (tissues) Method 446/1		
	Pyraclostrobin *per se* (ppm)	Residues hydrolyzable to BF 500-5, ppm pyraclostrobin equivalents [1]	Residues hydrolyzable to BF 500-8, ppm pyraclostrobin equivalents [2]	Total residues, ppm pyraclostrobin equivalents [3]
Whole Milk				
1	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02
4	--	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02
7	--	<0.01, <0.01, <0.01	<0.01, <0.01, 0.0124	<0.02, <0.02, <0.0224
10	--	<0.01, <0.01, <0.01	<0.01, <0.01, 0.011	<0.02, <0.02, <0.021
12	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.01, <0.01, 0.0119	<0.02, <0.02, <0.0219
15	--	<0.01, <0.01, <0.01	<0.01, 0.0126, 0.0135	<0.02, <0.0226, <0.0235
18	--	<0.01, <0.01, <0.01	<0.01, 0.0104, 0.0130	<0.02, <0.0204, <0.0230
21	--	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02
24	--	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02
27	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.01, <0.01, 0.0108	<0.02, <0.02, <0.0208
Skim Milk				
26	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.02, <0.02, <0.02
Milk Fat				
26	<0.01, <0.01, <0.01	<0.01, <0.01, <0.01	<0.01, 0.0368, 0.0461	<0.02, <0.0468, <0.0561
Fat				
29	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.1, <0.1, <0.1
Kidney				
29	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.1, <0.1, <0.1
Liver				
29	<0.05, <0.05, <0.05	0.0645, 0.0761, 0.0973	0.399, 0.426, 0.510	0.464, 0.502, 0.607
Muscle				
29	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.05, <0.05, <0.05	<0.1, <0.1, <0.1

[1] Pyraclostrobin and its metabolites hydrolyzable to BF 500-5 were determined in milk using the GC/MS method and in tissues using the LC/MS/MS method.

[2] Metabolites hydrolyzable to BF 500-8 were determined in milk using the GC/MS method and in tissues using the LC/MS/MS method.

[3] Total BF 500-5 and BF 500-8 residues, expressed as pyraclostrobin equivalents.

In the poultry feeding study, laying hens were orally dosed once daily for 30 consecutive days with pyraclostrobin at dose levels equivalent to 0.28 ppm (0.3x), 0.88 ppm (0.9x), and 3.01 ppm (3.0x). At the highest feeding level of 3.01 ppm, residues of pyraclostrobin and its metabolites hydrolyzable to BF 500-5 were less than the method LOQ (0.05 ppm) in all egg and tissue samples, except for one egg sample (Day 17) where residues of pyraclostrobin were detected at 0.064 ppm and <0.05 ppm upon re-analysis. Residue analysis of BF 500-8 was not conducted (the metabolism data show all metabolites hydrolyzable to BF 500-8 would be less than 10% TRR), but instead an isomeric compound (BF 500-9) was measured. Levels of BF 500-9 also were all <0.05 ppm.

Conclusions: Based on these dietary exposure levels and the residue data from the ruminant feeding study, the existing pyraclostrobin tolerances for milk (0.1 ppm), meat (0.1 ppm), fat (0.1 ppm), meat byproducts except liver (0.2 ppm), and liver (1.5 ppm) of cattle, goats, hogs, horses, and sheep are adequate to support the proposed uses. Tolerances for eggs and poultry are not needed based on data from the poultry feeding and metabolism studies [Category 180.6(a)(3)]. If in the future, the petitioner proposes a use which increases the dietary burdens of poultry, then the Category 3 situation will be re-evaluated.

860.1500 Crop Field Trials

The field trials conducted on fresh herbs (basil, chives, and dill) and avocados included a tank mixture of the pyraclostrobin test formulation (BAS 500 02F) with another active ingredient, boscalid (formulated as BAS 510 UCF). The field trials conducted on oats also reflect a tank mixture with metconazole (formulated as BAS 555 01F). Only the residue data from treatments with pyraclostrobin are reported in this Summary Document.

Field Trial Data Submitted Under PP#6E7105

Canola

DER Reference List 46925301.der.doc

BASF Corporation has submitted field trial data for pyraclostrobin on canola. Sixteen field trials were conducted during the 2005 growing season in NAFTA Growing Zones 5 (ND and SD, 1 trial each), 7 (ND, 1 trial), 11 (ID, 1 trial), and 14 (AB, 4 trials; SK, 5 trials; and MB, 3 trials). In each trial site, the 2.0 lb/gal EC formulation of pyraclostrobin was applied to established canola plants during pod development as two broadcast foliar sprays at 0.19-0.21 lb ai/A/application, with a 6-7 day retreatment interval, for a total rate of 0.39-0.41 lb ai/A (~1.0x the maximum proposed seasonal rate of 0.39 lb ai/A). At five locations, a separate treatment plot received two foliar broadcast sprays at 0.1 lb ai/A/application for a total rate of 0.20 lb ai/A. The latter treatment was included to provide bridging residue data for oilseed crops for which the maximum use rate may be lower than the proposed rate for canola. Applications were made using ground equipment (20-31 gal/A of spray volume) and included the use of an adjuvant. Single control and duplicate treated samples of canola seeds were harvested from each test site 20-22 days after the second treatment (DAT). At two sites treated with the higher rate, canola seed samples were collected at 0, 10, 21-22, 30, and 39-41 DAT to generate residue decline data. Samples were stored frozen for up to 7.6 months prior to analysis, an interval supported by

available storage stability data.

Samples of harvested canola seeds were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.005 ppm.

A summary of residue data from the canola field trials is presented in Table 8. The results show that following two applications of the 2.0 lb/gal EC formulation of pyraclostrobin reflecting PHI of 20-22 days, combined residues in/on canola seed were <0.04-0.27 ppm for samples (n = 32) treated at a total rate of 0.39-041 lb ai/A (1.0x) and were <0.04-0.11 ppm for samples (n = 10) treated at a total rate of 0.20 lb ai/A. The average combined residues were 0.08 and 0.06 ppm in/on samples treated at high and low rates, respectively. The residue decline data indicate that residues of pyraclostrobin decrease at longer preharvest intervals.

Table 8. Summary of Residue Data from Canola Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Four foliar sprays at 0.10 lb ai/A/application for a seasonal rate of 0.39 lb ai/A with a 21-day PHI.									
Canola seed	0.39-0.41	20-22	32	<0.04	0.27	0.25	0.05	0.08	0.06
	0.20	21-22	10	<0.04	0.11	0.10	0.04	0.06	0.03

Conclusions: The proposed use patterns of pyraclostrobin on canola and flax include foliar and seed treatments. The residue data included in the canola field study only reflect foliar use, and no seed treatment data were submitted. Based on the seeding rate typically used for canola (4-8 lb of seed per acre) and flax (20-30 lb of seed per acre), the proposed maximum seed treatment rate of 0.04 lb ai/100 lb of seed per acre would be equivalent to maximums of and 0.0032 lb ai/A for canola and 0.012 lb ai/A for flax, which are negligible compared to the maximum proposed seasonal rate of ~0.4 lb ai/A for foliar uses.

The submitted field trial data reflecting foliar uses for canola seed are adequate. The number and locations of field trials are in accordance with OPPTS Guideline 860.1500, and the conducted field trials reflect the maximum proposed foliar use pattern. The petitioner is currently proposing a crop group tolerance of 0.4 ppm for "Oilseed, group 20". According to a 6/14/06 memo by B. Schneider entitled "Reviewer's Guide and Summary of HED ChemSAC Approvals for Amending Crop Groups/Subgroups [40 CFR §180.41] and Commodity Definitions [40 CFR §180.1(h)]", the new Oilseed Crop Group 20 is being established to harmonize with Canada's Crop Group 20. The representative commodities for the crop group are rapeseed (canola varieties only), sunflower seed, and cottonseed. Flax seed, for which uses are being proposed as part of this petition, is a member of the rapeseed crop group. The memo further states that until the Federal Register is issued revising the Crop Group Regulation to establish the Oilseed Crop Group 20, tolerances for the representative commodities [rapeseed (canola seed), sunflower seed, and cottonseed] as well as all members of the crop group will be listed individually, and the tolerances will be identical for all members of that subgroup.

An individual pyraclostrobin tolerance for sunflower has already been established at 0.3 ppm in 40 CFR §180.582. The submitted residue data for rapeseed seed indicate that the maximum combined residues were 0.27 ppm in/on samples treated at 1x. The field trial data for canola seed were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends a tolerance of 0.45 ppm for canola seed. This recommended level is slightly higher than the petitioner's tolerance proposal of 0.4 ppm for "Oilseed, group 20" but does not vary by a factor of 5x. Based on the submitted field trial data, HED is recommending individual tolerances of 0.45 ppm for all oilseeds in 3 subgroups: 1) rapeseed (i.e., borage, crambe, cuphea, echium, flax seed, gold of pleasure, hare's ear mustard, lesquerella, lunaria, meadowfoam, milkweed, mustard seed, oil radish, poppy seed, rapeseed, sesame, and sweet rocket); 2) sunflower (i.e., Castor oil plant, Chinese tallowtree, Euphorbia, Evening primrose, Jojoba, Niger seed, Rose hip, Safflower, Stokes aster, Sunflower, Tallowwood, Tea oil plant, Vernonia); 3) cotton (only entry presently in this subgroup). Based on the submitted field trial data, HED is recommending individual tolerances of 0.45 ppm for all oilseeds in subgroups rapeseed, sunflower, and cotton. The canola seed data will be translated to all oilseeds in the rapeseed subgroup, and the sunflower data will be translated to all oilseeds in the sunflower subgroup. The petitioner is required to submit a revised Section F to propose individual tolerances for all above oilseeds at 0.45 ppm each.

Oats

DER Reference List 46902226.der.doc

BASF Corporation has submitted field trial data for pyraclostrobin on oats. Twelve field trials were conducted during the 2004 and 2005 growing season: eleven spring oat trials in NAFTA Growing Zones 1 (NY, 1 trial), 5 (IL, ND, WI, 1 trial each), 5B (QB, 1 trial), 6 (OK, 1 trial), 7 (ND and NE, 1 trial each), and 14 (AB, MB, and SK, 1 trial each); and one winter oat trial in Zone 2 (GA, 1 trial). The test formulation used in all trials was BAS 500 02F, which was identified as Headline® Fungicide (EPA Reg. No. 7969-186, 2.09 lb/gal EC). BAS 500 02F was applied at each test location as two broadcast sprays at 0.14-0.16 lb ai/A/application, with a 6-8 day retreatment interval, for a total rate of 0.29-0.31 lb ai/A (~1.0x the maximum proposed seasonal rate). Applications were initiated approximately 4 weeks prior to the harvest of mature grain or approximately 2 weeks prior to the cutting of hay. Applications were made using ground equipment (10-27 gal/A of spray volume) and included the use of an adjuvant.

Single control and duplicate treated samples of oat hay were harvested from each test site at 6-8 days after the last treatment (DAT). Grain and straw samples were harvested at 20-21 DAT. Grain and straw samples from the OK trial site were collected at 26 DAT due to adverse weather conditions that prevented harvest at the target PHI. At one site, hay samples were harvested at 0, 7, and 14 DAT, and grain/straw samples were harvested at 14, 21, 28 and 36 DAT to generate residue decline data. Samples were stored frozen for up to 12.4 months prior to analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the oat field trials is presented in Table 9. The results show that

following two spray applications of BAS 500 02F (EC formulation) totaling 0.29-0.31 lb ai/A (1.0x), combined residues ranged 0.10-0.75 ppm in/on grain (n = 24 samples) and 1.33-14.90 ppm in/on straw (n = 24) at 20-26 DAT. Combined residues were 2.38-14.83 ppm in/on hay (n = 24) at 6-8 DAT. The decline data show that pyraclostrobin residue remain relatively constant in oat commodities with increasing preharvest intervals.

Table 9. Summary of Residue Data from Oat Field Trials with Pyraclostrobin

Commodity	Total Applic.. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A. The proposed PHIs are 14 days for hay and green chopped oats (forage). No PHIs are proposed for grain and straw.									
Grain	0.29-0.31	20-26	24	0.10	0.75	0.64	0.35	0.33	0.18
Straw			24	1.33	14.90	13.40	3.92	4.70	3.07
Hay	0.29-0.31	6-8	24	2.38	14.83	14.46	6.00	6.25	3.20

Conclusions: The proposed use patterns of pyraclostrobin on oats include foliar and seed treatments. The supporting residue data included in the current petition only reflect foliar use, and no seed treatment data were submitted. Based on the seeding rate typically used for oats (50-120 lb of seed per acre), the proposed seed treatment rate of 0.005-0.01 lb ai/100 lb of seed per acre would be equivalent to 0.005-0.012 lb ai/A which is negligible compared to the maximum proposed seasonal rate of ~0.3 lb ai/A for foliar use.

The submitted field trial data reflecting foliar uses for oat grain, straw, and hay are adequate to fulfill data requirements pending submission revised Sections B and F. Based on the available data, a revised Section B is required to specify PHIs of 20-26 days for oat grain and straw and 6-8 days for oat hay. A revised Section F is required to amend the proposed tolerances as determined by the Agency's tolerance spreadsheet.

Geographic representation of residue data for oat grain, straw, and hay is not in full compliance with GLN 860.1500 requirements since only 12 trials were conducted; the guideline requires a total of 16 trials to establish individual tolerances for oat commodities. However, the petitioner has included Appendix J in the study report which documents correspondence between EPA and BASF regarding the "Proposal to EPA and PMRA for Reduction of the Number of Field Residue Sites Required to Set a Fungicide Tolerance in Small Grains (Wheat, Barley, Oats, and Rye)". Based on the total number of field trials conducted for small grains, it was reported that the conducted trials for oats should be adequate to set individual tolerances on wheat, barley, oats, and rye.

No residue data are submitted for oat forage. The petitioner did not provide residue data or propose a tolerance for oat forage because per the proposed label directions, applications are made after the growth stages at which oat is foraged. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for oat forage.

The field trial data for oat grain, straw, and hay were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends tolerances of 1.2 ppm for oat grain, 15 ppm for oat straw, and 18 ppm for hay. These recommended levels vary slightly from the petitioner's tolerance proposals of 1.0 ppm for oat grain and 17 ppm each for oat hay and straw.

Field Trial Data Submitted Under PP#6E7165

Herbs subgroup 19A

Basil

DER Reference List 47014803.der.doc

IR-4 has submitted field trial data for pyraclostrobin on basil. Four field trials were conducted in NAFTA Growing Zones 1 (NY, 1 trial), 3 (FL, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to basil as four directed foliar sprays at 0.20-0.21 lb ai/A/application for a total rate of 0.80-0.83 lb ai/A (2.7x the maximum proposed seasonal rate of 0.3 lb ai/A). Applications were made beginning when basil plants were at the vegetative/flowering stage and repeated on a 6- to 8-day retreatment interval using ground equipment (28-54 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of fresh basil were harvested from each test site at 0 and 3 days after treatment (DAT). Additional fresh basil samples were collected at 0 DAT and then dried according to simulated commercial practices in order to generate residue data for dried basil. Samples were stored frozen for up to 172 days prior to analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the basil field trials is presented in Table 10. The results show that following four spray applications of pyraclostrobin (BAS 500 02F) totaling 0.80-0.83 lb ai/A (2.7x), combined residues ranged 7.2-21.1 ppm in/on 8 samples of fresh basil harvested at 0 DAT, 1.3-7.5 ppm in/on 8 samples of fresh basil harvested at 3-4 DAT, and 40.1-80.6 ppm in/on dried basil harvested at 0 DAT. The average combined residues were 10.9 ppm in fresh basil harvested at 0 DAT, 4.8 ppm in fresh basil harvested at 3-4 DAT, and 67.5 ppm in dried basil harvested at 0 DAT. The processing of fresh basil to dried basil resulted in an increase of total residues, and the calculated processing factors of total residues ranged 4.6-9.0x with an average factor of 6.5x.

Table 10. Summary of Residue Data from Basil Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A with a 0-day PHI.									
Fresh basil	0.80-0.83	0	8	7.2	21.1	16.1	8.9	10.9	4.5
		3-4	8	1.3	7.5	7.4	4.9	4.8	2.6
Dried basil		0	4	40.1	80.6	80.6	74.7	67.5	18.5

Chives

DER Reference List 47014802.der.doc

IR-4 has submitted field trial data for pyraclostrobin on chives. Four field trials were conducted in NAFTA Growing Zones 2 (MD, 1 trial), 5 (OH, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to chives as four directed foliar sprays at 0.20-0.21 lb ai/A/application for a total rate of 0.81-0.83 lb ai/A (2.7x the maximum proposed seasonal rate of 0.3 lb ai/A). Applications were made beginning when chive plants were at the vegetative stage and repeated on a 6- to 8-day retreatment interval using ground equipment (24-50 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of fresh chives were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 115 days prior to analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the chive field trials is presented in Table 11. The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.81-0.83 lb ai/A (2.7x), combined residues ranged 0.7-8.8 ppm in/on 8 samples of fresh chives harvested immediately following the last treatment (0 DAT). The average combined residues in/on treated samples were 5.8 ppm.

Table 11. Summary of Residue Data from Chive Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A with a 0-day PHI.									
Chives	0.81-0.83	0	8	0.7	8.8	7.8	6.9	5.8	3.1

Dill

DER Reference List 47014801.der.doc

IR-4 has submitted field trial data for pyraclostrobin on dill. Four field trials were conducted in NAFTA Growing Zones 2 (MD, 1 trial), 3 (FL, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to dill as four directed foliar sprays at 0.19-0.21 lb ai/A/application for a total rate of 0.80-0.83 lb ai/A (2.7x the maximum proposed seasonal rate of 0.3 lb ai/A). Applications were made beginning when dill plants were at the vegetative growth stage through seed production; the retreatment intervals were 6 to 8 days. Foliar sprays were made using ground equipment (28-62 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of fresh dill and dill seeds were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 171 days prior to

analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the dill field trials is presented in Table 12. The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.80-0.83 lb ai/A (2.7x), combined residues at 0 DAT ranged 3.98-19.54 ppm in/on 8 samples of fresh dill and 3.60-22.60 ppm in/on 6 samples of dill seed. The average combined residues were 10.46 ppm in/on fresh dill and 14.45 ppm in/on dill seed.

Table 12. Summary of Residue Data from Dill Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A with a 0-day PHI.									
Fresh Dill	0.81-0.82	0	8	3.98	19.54	19.01	9.66	10.46	5.79
Dill Seed	0.80-0.83	0	6	3.60	22.60	21.20	18.30	14.45	8.34

Conclusions: The submitted residue data for basil (fresh and dried) and chives, the representative commodities of Herbs subgroup 19A, along with those data submitted for dill (fresh and seed) are adequate with respect to geographic representation of data. However, the field trials were conducted at an exaggerated total application rate of ~0.8 lb ai/A (2.7x the maximum proposed seasonal rate of 0.3 lb ai/A). As a result, these data are not indicative of the magnitude of the residue following applications at the proposed use pattern.

The petitioner has submitted a product label for Pristine® Fungicide and this label directions state, "Do not apply more than 37 oz/A per season", which equals 0.3 lb pyraclostrobin. HED, at times, allows a revised Section B to reflect this different rate used in the field trials. **However**, the proposed formulation contains two active ingredients, i.e., pyraclostrobin (12.8%) and boscalid (25.2%). A review of the boscalid data (See memo of 11/27/2007, C. Olinger), shows that boscalid was applied only twice but by using a different formulation, for a total of 0.59 lb a.i./A. This matches the proposed use rate for boscalid. If applied at the proposed label rate for pyraclostrobin (2 applications/season, 0.3 lb ai/A/season), then boscalid would be applied at the proposed rate (2 applications/season, 0.58 lb ai/A/season). However, if this combined formulation is applied at the exaggerated rate as representative of the submitted field trials, pyraclostrobin would be applied at 0.8 lb/ai/A/season, while boscalid would be applied at 1.58 lb ai/A/season (2.7x). Although the recommended pyraclostrobin tolerance would cover any pyraclostrobin residues at 4 applications/season, boscalid residues at this treatment rate would probably exceed the recommended tolerance for boscalid. Thus, if it is the intent of the petitioner to propose this combined formulation for herbs (subgroup 19A), then a simple label revision will not solve the problem. The data only support 2 applications of boscalid, and not 4 applications. The proposed label cannot be revised.

Residue decline data were not submitted and are not required for the purpose of this petition since GLN 860.1500 states that decline data will typically not be required for each minor crop needing three or fewer total trials to establish an individual tolerance.

The field trial data for all fresh herbs (basil, chives, and dill) reflecting the exaggerated rate were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting*

Pesticide Tolerances Based on Field Trial Data SOP to determine an appropriate tolerance level; see Appendix II. The tolerance spreadsheet recommends a tolerance of 25.0 ppm for Herbs subgroup 19A. This tolerance level is slightly lower than the level (30.0 ppm) initially proposed by the petitioner. Additional data from the basil and dill field trials suggest that tolerances are needed for dried basil leaves at 85 ppm and dill seed at 25 ppm. Based on the above discussion, this recommended tolerance would be higher than needed when the proposed label directions (2 applications/season) are followed.

Avocado

DER Reference List 47014804.der.doc

IR-4 has submitted field trial data for pyraclostrobin on avocados. Seven field trials were conducted in NAFTA Growing Zones 10 (CA, 4 trials) and 3 (FL, 3 trials) during the 2002 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to established avocado trees as four directed foliar sprays at 0.18-0.20 lb ai/A/application for a total rate of 0.73-0.78 lb ai/A (2.6x the maximum proposed seasonal rate of 0.3 lb ai/A). Applications were made at the fruiting stage and repeated on a 6- to 8-day retreatment interval using ground equipment (152-176 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of avocado fruits were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 182 days prior to analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the avocado field trials is presented in Table 13. The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.73-0.78 lb ai/A (2.6x), combined residues ranged 0.08-0.48 ppm in/on avocados (n=14 samples) harvested at 0 DAT. The average combined residues in/on treated fruit samples were 0.18 ppm.

Table 13. Summary of Residue Data from Avocado Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT[3]	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A with a 0-day PHI.									
Avocado	0.73-0.78	0	14	0.08	0.48	0.40	0.16	0.18	0.11

Conclusions: The submitted residue data for avocado are inadequate to fulfill data requirements because the field trials were conducted at exaggerated rates. Not only were the individual application rates higher than the label maximum, but two additional applications beyond what is specified on the label were applied, resulting in a seasonal application rates ~2.5 – 2.7x the maximum proposed seasonal label rate. While the submitted data represent an overestimate of the residues expected from the proposed use, the degree of exaggeration can not be determined. The use of the proportionality concept (See CHEMSAC, minutes, 05/09/2007) to adjust residues downward is not considered appropriate since the data included more applications than the desired use. Given that the proposed use is for late season foliar application, and includes a 0-day preharvest interval, for the purpose of this IR-4 petition, HED will use the submitted data to

support a tolerance for avocado. However, since HED considers that the tolerance may need to be reduced, and further since this data is being translated to support a wide number of tropical/subtropical fruits, HED requests that the petitioner provide an additional two to three field trials at the label rate (2 applications, total 0.3 lb ai/season) as a condition of registration.

The field trial data for avocado reflecting the exaggerated rate were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine an appropriate tolerance level; see Appendix II. The tolerance spreadsheet recommends a tolerance of 0.6 ppm for avocado which is slightly lower than the level (0.7 ppm) initially proposed by the petitioner.

The submitted data for avocado may be translated to other tropical fruits for which uses are proposed pending label revision as specified above. HED is in the process of revising the Commodity Definitions listed under 40 CFR §180.1(h) to make the tropical/subtropical fruit avocado a general commodity; see 6/14/06 memo by B. Schneider entitled "Reviewer's Guide and Summary of HED ChemSAC Approvals for Amending Crop Groups/Subgroups [40 CFR §180.41] and Commodity Definitions [40 CFR §180.1(h)]". The specific commodities included in the general definition for avocado include black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple. Until the regulations have been finalized in the Federal Register, separate tolerances are needed for each specific commodity, at the same level as the respective general commodity tolerance. Therefore, the petitioner is required to submit a revised Section F to propose a tolerance of 0.6 ppm each for avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple.

Field Trial Data Submitted Under PP#7E7245

Barley

DER Reference List 47190501.der.doc

IR-4 has submitted field trial data for pyraclostrobin on barley. Four field trials were conducted during the 2004 and 2005 growing season in NAFTA Growing Zones 8 (CO, 2 trials) and 11 (ID, 2 trials). Pyraclostrobin (2.0 lb/gal EC) was applied at each test location as two broadcast foliar sprays at 0.143-0.152 lb ai/A/application, with retreatment interval of 11-14 days, for totals of 0.29-0.30 lb ai/A. All applications were made using ground equipment (29-37 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of barley grain and straw samples were harvested at 14-15 DAT and 21-23 DAT. Samples were stored frozen for up to 9.6 months prior to analysis, an interval supported by available storage stability data. The collected samples were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 which is adequate for data collection based on acceptable concurrent method recoveries.

A summary of residue data from the barley field trials is presented in Table 14. The results show that following two spray applications of an EC formulation of pyraclostrobin totaling 0.29-0.30 lb ai/A, combined residues at 14-15 DAT were 0.54-0.98 ppm in/on grain and 1.7-4.0 ppm in/on straw. The average combined residues at 14-15 DAT were 0.80 ppm for grain and 2.7 ppm for straw.

Table 14. Summary of Residue Data from Barley Field Trials with Pyraclostrobin									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels of Pyraclostrobin and its Metabolite BF 500-3 (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Proposed use pattern: Two foliar sprays at 0.15 lb ai/A/application for a seasonal rate of 0.3 lb ai/A with a 14-day PHI.									
Grain	0.29-0.30	14-15	8	0.54	0.98	0.93	0.85	0.80	0.16
Straw			8	1.7	4.0	3.8	2.8	2.7	0.79
Grain	0.29-0.30	21-23	8	0.11	0.49	0.45	0.39	0.34	0.14
Straw			8	0.65	2.2	1.8	1.4	1.3	0.50

Conclusions: The submitted field trial data for barley grain and straw are adequate to fulfill data requirements pending submission a revised Section F to amend the proposed tolerances as determined by the Agency's tolerance spreadsheet.

Geographic representation of residue data for barley grain and straw are adequate. No residue data were submitted for barley forage, and these data are normally required to support the amended use pattern. However, the petitioner did not provide residue data or propose a tolerance for barley hay because per the proposed label directions, applications are made after the growth stages at which barley hay is harvested. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for barley hay.

The field trial data for barley grain and straw were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends tolerances of 1.4 ppm for barley grain and 6.0 ppm for barley straw. These recommended levels vary slightly from the petitioner's tolerance proposals of 1.3 ppm for barley grain and 9.0 ppm for barley straw.

860.1520 Processed Food and Feed

Basil

Residue data on dried basil leaves are included and summarized in the Magnitude of the Residue section for fresh basil.

Barley

Barley: No residue data for the barley processed commodities (bran and pearled) are submitted. However, data from the wheat processing studies (MRID #'s 45118620 and 45321101) can be translated to adequately support the proposed use on barley. Based on the wheat studies, residues are not expected to concentrate in barley processed commodities.

Canola

DER Reference List 46925301.del.doc

BASF Corporation has submitted a processing study with pyraclostrobin on canola. Samples used for processing were generated from a field trial conducted during the 2005 growing season in Saskatchewan, Canada. The 2.0 lb/gal EC formulation of pyraclostrobin was applied to

established canola plants during pod development as two broadcast foliar sprays at 0.6 lb ai/A/application, with a 6-day retreatment interval, for a total rate of 1.2 lb ai/A (3.3x the field trial application rate). Applications were made using ground equipment (22 gal/A of spray volume) and included the use of an adjuvant. Single control and duplicate treated samples of canola seeds were harvested from the test site 21 days after the final spray treatment. The harvested canola bulk seed samples were frozen immediately and shipped to a processing facility where they were processed into meal and refined oil using simulated commercial procedures. Canola seed, meal, and refined oil samples were stored frozen for up to 3.3, 2.5, and 1.8 months, respectively, prior to residue analysis. The storage conditions and durations of samples are supported by available storage stability data.

Samples of canola seed and its processed commodities were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.005 ppm.

A summary of residue data from the canola processing study is presented in Table 14. The results indicate that the combined residues of pyraclostrobin and its metabolite BF 500-3 averaged 0.05 ppm in/on canola seed treated at a total rate of 1.2 lb ai/A. Following processing, combined residues were <0.04 ppm in meal and 0.06 ppm in refined oil. The equivalent processing factors from these data are 0.8x for meal and 1.2x for refined oil. The maximum theoretical concentration factors for canola processed commodities, based on separation into components, are 1.9x for meal and 3.0x for oil (OPPTS GLN 860.1520, Table 3).

Table 15. Residue Data from Canola Processing Study with Pyraclostrobin.

RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Combined Residues of Pyraclostrobin and its BF 500-3 Metabolite (ppm)			Processing Factor
				Pyraclostrobin	BF-500-3	Combined	
Canola seed	Seed	1.2	21	0.02, 0.03	<0.02, <0.02	<0.04, 0.05	--
	Meal			<0.02, 0.03	<0.02, <0.02	<0.04, <0.04	0.8x
	Refined oil			0.04, 0.04	0.02, 0.03	0.05, 0.07	1.2x

Conclusions: The canola processing study is acceptable to satisfy data requirements. The treated samples of canola seed (RAC) used for processing bore average combined residues of 0.05 ppm. Following processing of the RAC, total residues concentrated marginally in refined oil (1.2x) but reduced in meal (0.8x). The maximum expected combined residues in refined oil, resulting from the proposed use, is 0.3 ppm. This value was calculated by multiplying the processing factor of 1.2x by the HAFT residue of 0.25 ppm (see Table 8). The maximum expected residue in refined oil is identical to the recommended tolerance for the RAC (canola seed). Based on this determination, tolerances need not be established for the processed commodities of canola.

Oat

Oats: No residue data for the oat processed commodities (flour and groats/rolled oats) are submitted. However, data from the wheat processing studies (MRID #'s 45118620 and

45321101) can be translated to adequately support the proposed use on oat. Based on the wheat studies, residues are not expected to concentrate in oat processed commodities

860.1650 Submittal of Analytical Reference Standards

Analytical standards for pyraclostrobin and its regulated metabolites are currently available in the EPA National Pesticide Standards Repository. Analytical reference standards of pyraclostrobin and its regulated metabolites must be supplied and supplies replenished as requested by the Repository. The reference standards should be sent to the Analytical Chemistry Lab, which is located at Fort Meade, at the following address:

USEPA
National Pesticide Standards Repository/Analytical Chemistry Branch/OPP
701 Mapes Road
Fort George G. Meade, MD 20755-5350

(Note that the mail will be returned if the extended zip code is not used.)

860.1850 Confined Accumulation in Rotational Crops

HED Metabolism Assessment Review Committee Decision Memo, DP# 278044, 10/9/01, L. Cheng
Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

An adequate confined rotational crop study was reviewed in PP#0F6139. The study showed that the metabolism of pyraclostrobin in rotated crops is similar but more extensive than that in primary crops. Pyraclostrobin undergoes demethoxylation to yield BF 500-3, followed by further degradation to medium polar and polar metabolites, and subsequent conjugation reactions and incorporation into natural products. The HED MARC has determined that the residues of concern in rotational crops consist of pyraclostrobin and metabolite BF 500-3.

860.1900 Field Accumulation in Rotational Crops

Residue Chemistry Memo, DP# 269668, 11/28/01, L. Cheng (PP#0F6139)

A limited field rotational crop study was reviewed in PP#0F6139. The results indicate that residues of pyraclostrobin and its metabolite BF 500-3 were each less than the method LOQ (<0.02 ppm) in/on rotational crop matrices (radish, roots and tops; cabbage, with and without wrapper leaves; and wheat forage, hay, and grain) planted 14 days following the last of six sequential foliar applications to the primary crop, cucumbers, of the 2 lb/gal EC formulation at 0.19-0.20 lb ai/A/application. Residues of pyraclostrobin in/on one sample of wheat straw from the CA test site were at the LOQ (0.02 ppm), but residues of pyraclostrobin in/on a replicate sample from the same plot were below the LOQ (0.012 ppm) for an average residue of <0.02 ppm. Residues of metabolite BF 500-3 were nondetectable (<0.02 ppm) in/on all samples of wheat straw.

The registered pyraclostrobin end-use product labels presently specify a 14-day plantback interval restriction for all crops that are not registered. No rotational crop restrictions are listed in the Section B of the subject petitions.

Conclusions: An acceptable limited field rotational crop study with pyraclostrobin has been submitted and reviewed. Based on the available data, the petitioner needs to submit a revised Section B to specify a 14-day plantback interval restriction for all annual crops that are not registered.

860.1550 Proposed Tolerances

The HED Metabolism Assessment Review Committee (MARC memo of 10/9/01, DP# 278044, L. Cheng) has determined that for purposes of tolerance and dietary risk assessments, the residues of concern in plant and rotational crop commodities include pyraclostrobin and its desmethoxy metabolite, BF 500-3. The residues of concern in livestock commodities include pyraclostrobin and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol (BF 500-5) and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol (BF 500-8).

Pyraclostrobin tolerances for plant commodities are listed in 40 CFR §180.582 (a)(1) and are expressed in terms of the combined residues of the fungicide pyraclostrobin (carbamic acid, [2-[[[1-(4-chlorophenyl)-1H- pyrazol-3-yl]oxy]methyl]phenyl]methoxy-, methyl ester) and its desmethoxy metabolite (methyl N-[[[1-(4-chlorophenyl)-1H-pyrazol-3-yl]oxy]methyl]phenyl carbamate), expressed as parent compound.

Pyraclostrobin tolerances for animal commodities are listed in 40 CFR §180.582 (a)(2) and are expressed in terms of the combined residues of the fungicide pyraclostrobin and its metabolites convertible to 1-(4-chlorophenyl)-1H-pyrazol-3-ol and 1-(4-chloro-2-hydroxyphenyl)-1H-pyrazol-3-ol, expressed as parent compound.

The tolerance expression proposed by BASF in PP#6E7105 is consistent with the tolerance definition for plant commodities listed in 40 CFR §180.582 (a)(1). The tolerance expression proposed by IR-4 in PP#6E7165 is expressed as pyraclostrobin *per se* and should be amended to include all pyraclostrobin residues of concern.

The submitted field trial data for canola seed are adequate. Although adequate residue data have been submitted and a tolerance of 0.3 ppm has been established for sunflower seed, the other representative member of the new Oilseed Crop Group 20, a crop group tolerance will not be appropriate at this time until the Federal Register is issued revising the Crop Group Regulation to establish the Oilseed Crop Group 20. The field trial data for canola seed were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends a tolerance of 0.45 ppm for canola seed. Based on the submitted field trial data, HED is recommending individual tolerances of 0.45 ppm for all oilseeds in 3 subgroups: 1) rapeseed (i.e., borage, crambe, cuphea, echium, flax seed, gold of pleasure, hare's ear mustard, lesquerella, lunaria, meadowfoam, milkweed, mustard seed, oil radish, poppy seed, rapeseed, sesame, and sweet rocket); 2) sunflower (i.e., Castor oil plant, Chinese tallowtree, Euphorbia, Evening primrose, Jojoba, Niger seed, Rose hip, Safflower,

Stokes aster, Sunflower, Tallowwood, Tea oil plant, Vernonia); 3) cotton (only entry presently in this subgroup). Based on the submitted field trial data, HED is recommending individual tolerances of 0.45 ppm for all oilseeds in subgroups rapeseed, sunflower, and cotton. The canola seed data will be translated to all oilseeds in the rapeseed subgroup, and the sunflower data will be translated to all oilseeds in the sunflower subgroup. The petitioner is required to submit a revised Section F to propose individual tolerances for all above oilseeds at 0.45 ppm each.

The submitted field trial data for oat grain, straw, and hay are adequate pending label revision to specify PHIs of 20-26 days for oat grain and straw and 6-8 days for oat hay. The field trial data for oat grain, straw, and hay were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends tolerances of 1.2 ppm for oat grain, 15 ppm for oat straw, and 18 ppm for hay. The petitioner did not provide residue data or propose a tolerance for oat forage because per the proposed label directions, applications are made after the growth stages at which oat is foraged. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for oat forage.

The submitted field trial data for basil (fresh and dried) and chives, the representative commodities of Herbs subgroup 19A, along with those data submitted for dill (fresh and seed) are inadequate because the trials were conducted at an exaggerated rate of ~0.8 lb ai/A (2.7x). The submitted data may, however, be used to support the recommended subgroup tolerance.

The field trial data for all fresh herbs (basil, chives, and dill) reflecting the exaggerated rate were entered into the Agency's tolerance spreadsheet to determine an appropriate tolerance level; see Appendix II. The tolerance spreadsheet recommends a tolerance of 25.0 ppm for Herbs subgroup 19A. Additional data from the basil and dill field trials suggest that tolerances are needed for dried basil leaves at 85 ppm and dill seed at 25 ppm.

The submitted field trial data for avocado are inadequate because the trials were conducted at an exaggerated rate (~2.6x) and no residue decline data were submitted. The submitted data may, however, be used to support the proposed tolerance for avocado. The field trial data for avocado reflecting the exaggerated rate were entered into the Agency's tolerance spreadsheet to determine an appropriate tolerance level; see Appendix II. The tolerance spreadsheet recommends a tolerance of 0.6 ppm for avocado. Because of the exaggerated rate, the recommended tolerance would probably be higher than needed.

The submitted data for avocado may be translated to other tropical fruits (black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple) for which uses are proposed pending label revision. HED is in the process of revising the Commodity Definitions listed under 40 CFR §180.1(h) to make the tropical/subtropical fruit avocado a general commodity. The specific commodities included in the proposed general definition for avocado include black sapote, canistel, mamey sapote, mango, papaya, sapodilla, and star apple. Until the regulations have been finalized in the Federal Register, separate tolerances are needed for each specific commodity, at the same level as the respective general commodity tolerance.

The submitted field trial data for barley grain and straw are adequate. The field trial data for barley grain and straw were entered into the Agency's tolerance spreadsheet as specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* SOP to determine appropriate tolerance levels; see Appendix II. The tolerance spreadsheet recommends tolerances of 1.4 ppm for barley grain and 6.0 ppm for barley straw. No residue data were submitted for barley forage, and these data are normally required to support the amended use pattern. However, the petitioner did not provide residue data or propose a tolerance for barley hay because per the proposed label directions, applications are made after the growth stages at which barley hay is harvested. Based on the current proposed use patterns, the Agency will not require residue data or a tolerance for barley hay.

An acceptable canola processing study has been submitted, and the results suggest that no tolerances are required for the processed commodities of canola. An oat processing study is required to support the proposed use on oats.

An acceptable limited field rotational crop study is available. No rotational crop tolerances are required pending label revision to specify a plantback interval of 14 days for all annual crops that are not registered.

Adequate cattle and poultry feeding studies are available. The existing pyraclostrobin tolerances for milk, meat, fat, meat byproducts except liver, and liver of cattle, goats, hogs, horses, and sheep were reassessed, and no adjustments are needed. Tolerances for eggs and poultry are not needed at this time based on data from the poultry feeding and metabolism studies [Category 180.6(a)(3)].

The Codex Alimentarius Commission has established maximum residue limits (MRLs) for residues of pyraclostrobin at 0.5 ppm for oats and barley grain, and at 0.05 ppm for papaya (see Appendix I). The US tolerance level and residue definition both differ from Codex for all three commodities because of the application rates. There are no Canadian or Mexican MRLs for pyraclostrobin for the crop commodities discussed in this Summary Document.

A summary of the recommended tolerances for the crop commodities discussed in this Summary Document is presented in Table 15. The petitioner should submit a revised Section F reflecting the recommended tolerances and commodity definitions presented in Table 16.

Table 16. Tolerance Summary for Pyraclostrobin.

Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Tolerances Proposed Under PP#6E7105			
Oats grain	1.0	1.2	Tolerance recommendations are tentative pending submission of a revised Section B to specify PHIs of 20-26 days for oat grain and straw and 6-8 days for oat hay. *Oat, grain; oat, hay, and oat straw.*
Oats, hay	17	18	
Oats, straw	17	15	
Oilseed, group 20	0.4	Canola, seed at 0.45 ppm; Flax, seed at 0.45 ppm	A crop group tolerance will not be appropriate at this time until the Federal Register is issued revising the Crop Group Regulation to establish the Oilseed Crop Group 20. In the interim, HED is recommending individual tolerances on all oilseeds to be listed in the rapeseed subgroup.
Tolerances Proposed Under PP#6E7165			
Herb subgroup 19A, fresh herb	30.0	25	Tolerance recommendation is based on exaggerated field trial data. *Herbs subgroup 19A*
Avocado	0.7	0.6	Tolerance recommendation is tentative pending submissions of additional field trial data.

Table 16. Tolerance Summary for Pyraclostrobin.			
Commodity	Proposed Tolerance (ppm)	Recommended Tolerance (ppm)	Comments; *Correct Commodity Definition*
Tolerances Proposed Under PP#7E7245			
Barley, grain	1.3	1.4	Adequate field trial data are available on barley based on regional use.
Barley, straw	9.0	6.0	
Sapote, black	0.7	0.6	Tolerance recommendations are based on residue data translated from avocado.
Canistel	0.7	0.6	
Sapote, mamey	0.7	0.6	
Mango	0.7	0.6	
Papaya	0.7	0.6	
Sapodilla	0.7	0.6	
Star Apple	0.7	0.6	
Additional Tolerances That Need to be Proposed Under PP#6E7105			
Borage, Crambe, Cuphea, Echium, Flax seed, Gold of pleasure, Hare's ear mustard, Lesquerella, Lunaria, Meadowfoam, Milkweed, Mustard seed, Oil radish, Poppy seed, Rapeseed, Sesame, Sweet rocket (rapeseed subgroup); Castor oil plant, Chinese tallowtree, Euphorbia, Evening primrose, Jojoba, Niger seed, Rose hip, Safflower, Stokes aster Sunflower, Tallowwood, Tea oil plant, Vernonia (sunflower subgroup); Cotton (cotton subgroup)	none	0.45	HED is recommending individual tolerances on all oilseeds to be listed in the rapeseed subgroup.
Additional Tolerances That Need to be Proposed Under PP#6E7165			
Basil, dried leaves	–	85	Tolerance recommendation is based on exaggerated field trial data. *Herbs subgroup 19A*
Dill, seed	–	25	

References

DP#: None
Subject: Reviewer's Guide and Summary of HED ChemSAC Approvals for Amending Crop Groups/Subgroups [40 CFR §180.41] and Commodity Definitions [40 CFR §180.1(h)]
From: B. Schneider
To: B. Madden
Dated: 6/14/05
MRIDs: None

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data. EPA File Symbols:
From: L. Cheng
To: C. Giles-Parker/J. Bazuin
Dated: 11/28/01

MRIDs: 45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

DP#: 278044
Subject: PP# 0F06139. PC Code 099100. Pyraclostrobin. Outcome of the HED Metabolism Assessment Review Committee (MARC) Meeting Held on September 20, 2001.
From: L. Cheng
To: Y. Donovan
Dated: 10/09/01
MRIDs: None

DP#: 269850
Subject: PP# 0F06139. Pyraclostrobin (BAS 500F) in or on Various Crops. Request for Tolerance Method Validation (TMV) Trial.
From: L. Cheng
To: F. D. Griffith, Jr.
Dated: 11/8/00
MRIDs: 45118505, 45118504, 45118509, 45118510, 45118501, 45118503, 45118507, 45118514

Attachments:
Appendix I - International Residue Limit Status sheet
Appendix II - Tolerance Assessment Calculations

RDI: TMorton 012408; SHummel 021208
Petition Number(s): PP#6E7105, PP#6E7165, and PP#7E724
DP Barcodes: 343754, 345965, and 348700
PC Code: 099100

Template Version September 2005

Appendix I – International Residue Limits

INTERNATIONAL RESIDUE LIMIT STATUS			
Chemical Name: methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxy carbamate	Common Name: Pyraclostrobin	☐ Proposed tolerances ☒ Reevaluated tolerance ☐ Other	Date: 12/20/07
Codex Status (Maximum Residue Limits)		U. S. Tolerances	
☐No Codex proposal step 6 or above ☐No Codex proposal step 6 or above for the crops requested		Petition Numbers: 6E7105, 6E7165, and 7E7245 DP#s: 334535, 336189, and 343754 Other Identifier:	
Residue definition (step 8/CXL): pyraclostrobin (fat soluble)		Reviewers/Branch: B. Cropp-Kohlligan, G. Otakie, J. Stokes / RRB4	
		Residue definition in PP#6E7105, PP#6E7165,and PP#7E7245: Combined residues of pyraclostrobin and BF 500-3, expressed as pyraclostrobin.	

Crop (s)	MRL (mg/kg)	Crop(s)	Recommended Tolerance (ppm)
Oats	0.5	PP#6E7105	
Papaya	0.05	Oats grain	1.2
Barley	0.5	Oats, hay	18
		Oats, straw	15
		Canola, seed	0.45
		Flax, seed	0.45
		Borage	0.45
		Crambe	0.45
		Cuphea	0.45
		Echium	0.45
		Flax seed	0.45
		Gold of pleasure	0.45
		Hare's ear mustard	0.45
		Lesquerella	0.45
		Lunaria	0.45
		Meadowfoam	0.45
		Milkweed	0.45
		Mustard seed	0.45
		Oil radish	0.45
		Poppy seed	0.45
		Rapeseed	0.45
		Sesame	0.45
		Sweet rocket	0.45
		Castor oil plant	0.45
		Chinese tallowtree	0.45
		Euphorbia	0.45
		Evening primrose	0.45
		Jojoba	0.45
		Niger seed	0.45
		Rose hip	0.45
		Safflower	0.45
		Stokes aster	0.45
		Sunflower	0.45
		Tallowwood	0.45
		Tea oil plant	0.45
		Vernonia	0.45
		Cotton	0.45
		PP#6E7165	
		Herb subgroup 19A, fresh herb	25
		Basil, dried leaves	85
		Dill, seed	25
		Avocado	0.6
		Sapote, black	0.6
		Canistel	0.6
		Sapote, mamey	0.6
		Mango	0.6

		Papaya	0.6
		Sapodilla	0.6
		Star Apple	0.6
		PP#7E7245	
		Barley, grain	1.4
		Barley, straw	6.0
Limits for Canada		**Limits for Mexico**	
☒No Limits ☐No Limits for the crops requested		☒No Limits ☐No Limits for the crops requested	
Residue definition:		Residue definition:	
Crop(s)	MRL (mg/kg)	Crop(s)	MRL (ppm)
Notes/Special Instructions:			

Appendix II - Tolerance Assessment Calculations

The Agency's *Guidance for Setting Pesticide Tolerances Based on Field Trial Data* was utilized for determining appropriate tolerance levels for the Herbs subgroup 19A, avocado, oat grain, oat straw, oat hay, barley grain and barley straw as the combined residues of pyraclostrobin and its metabolite BF 500-3 were readily quantifiable (>LOQ) in/on these commodities. Since ~40% (13 of 32 samples) of the field trial sample results for canola seed were below the LOQ, maximum likelihood estimation (MLE) procedures were needed to impute censored values. The residue data for canola seed were first entered into the MLE spreadsheet to obtain the censored values and the pyraclostrobin-canola seed (MLE) dataset was then entered into the tolerance spreadsheet.

The dataset used to establish tolerances for pyraclostrobin residues in/on fresh herbs reflect four broadcast foliar applications totaling 0.80-0.83 lb ai/A and a PHI of 0 day (Table II-1). The dataset used for avocado reflect four directed broadcast foliar applications totaling 0.73-0.78 lb ai/A and a PHI of 0 days (Table II-2). The dataset used for oat grain, hay, and straw reflects two broadcast foliar applications totaling 0.29-0.31 lb ai/A (Table II-3). The dataset used for barley grain and straw reflects two broadcast foliar applications totaling 0.29-0.30 lb ai/A (Table II-4). The dataset used for canola seed reflects two broadcast foliar applications totaling 0.39-0.41 lb ai/A (Table II-5). As specified by the *Guidance for Setting Pesticide Tolerances Based on Field Trial Data,* the field trial application rates were within 25% of each other, and the PHIs are consistent with the proposed label.

The residue datasets for pyraclostrobin on the above commodities were entered into the tolerance spreadsheet. Visual inspection of the lognormal probability plots (Figures II-1, 3, 5, 7, 9, 11, 13, and 15) indicates that the datasets are reasonably lognormal, with the exception of Herbs subgroup 19A. The results from the Shapiro-Francia test statistic (Figures II-2, 4, 6, 8, 10, 12, 14, and 16) indicate that the assumption of lognormality is correct for all commodities except for Herbs subgroup 19A.

The tolerance spreadsheet calculates and recommends of 25 ppm for Herbs subgroup 19A, 0.6 ppm for avocado, 1.2 ppm for oat grain, 18 ppm for oat hay, 15 ppm for oat straw, 1.4 ppm for barley grain, 6.0 ppm for barley straw, and 0.45 ppm for canola seed.

Table II-1; Dataset Used to Calculate Tolerance Level for Pyraclostrobin on Fresh Herbs			
Regulator:	EPA		
Chemical:	Pyraclostrobin		
Crop:	Herbs Subgroup 19A		
PHI:	0 days		
App. Rate:	4 x 0.2 lb ai/A/application		
Submitter:	IR-4		
MRID Citations:	MRIDs 470148-01 through -03		
	Combined Residues		
	Fresh Dill	Fresh Chives	Fresh Basil
	19.54	6.85	8.52
	5.74	8.79	9.16
	10.27	7.97	21.07
	3.98	0.71	8.08
	18.48	6.96	7.21
	9.04	6.87	12.97
	10.8	7.05	11.09
	5.85	1.1	8.7

Figure II 1: Lognormal Probability Plot of Pyraclostrobin on Fresh Herbs

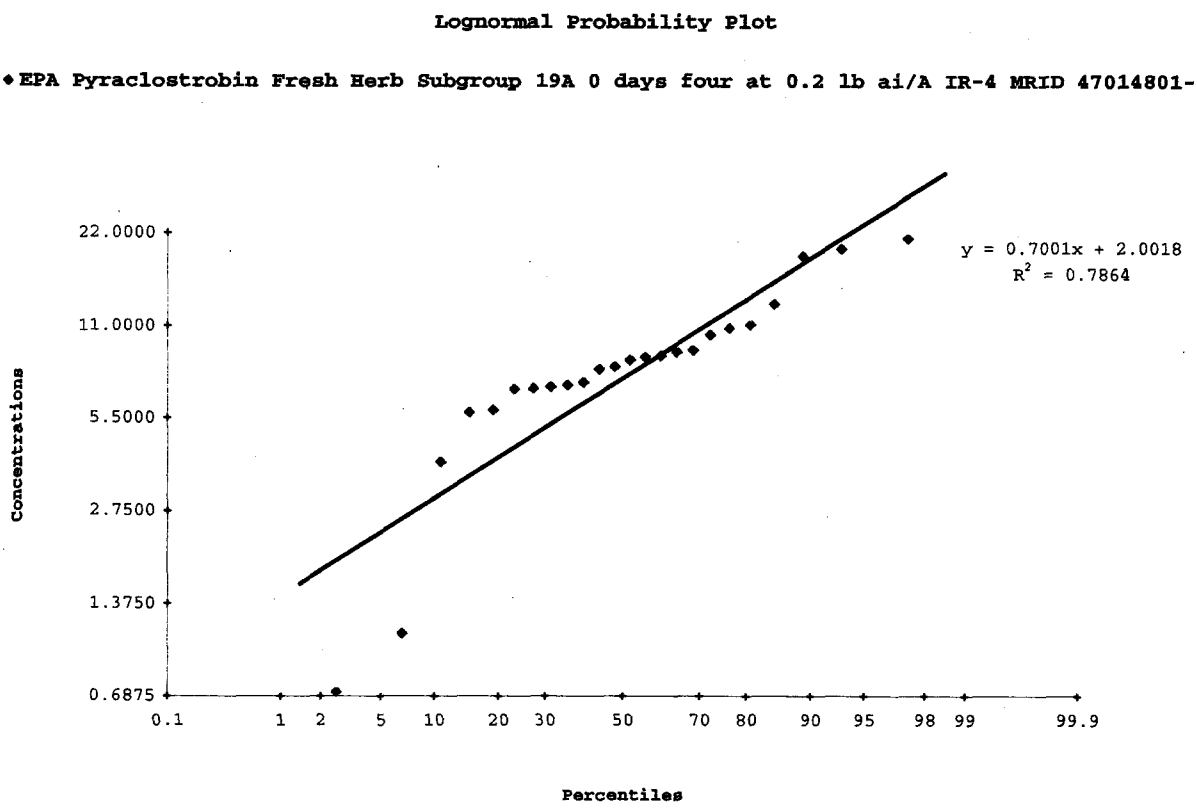


Figure II 2: Data Summary for Residues of Pyraclostrobin on Fresh Herbs

Regulator: EPA
Chemical: Pyraclostrobin
Crop: esh Herb Subgroup 19A
PHI: 0 days
App. Rate: four at 0.2 lb ai/A
Submitter: IR-4
MRID Citation: MRID 47014801-3

n: 24
min: 0.71
max: 21.07
median: 8.30
average: 9.03

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	18 (25)	25 (25)	25 (--)
EU Method I Log Normal	30 **(45)**	**45** (85)	80 (--)
EU Method II Distribution-Free	25		
California Method μ + 3σ	**25**		
UPLMedian95th	**50**		
Approximate Shapiro-Francia Normality Test	0.7864 p-value <= 0.01: Reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Table II-2: Data Used to Calculate Tolerance of Pyraclostrobin in/on Avocado	
Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Avocado
PHI:	0 days
Application Rate:	4 x 0.2 lb ai/A/application
Submitter:	IR-4
MRID Citation:	MRID 47014804
	Combined Residues
	0.08
	0.09
	0.09
	0.11
	0.12
	0.13
	0.14
	0.17
	0.17
	0.18
	0.19
	0.26
	0.31
	0.48

Figure II 3: Lognormal Probability Plot of Pyraclostrobin in/on Avocado

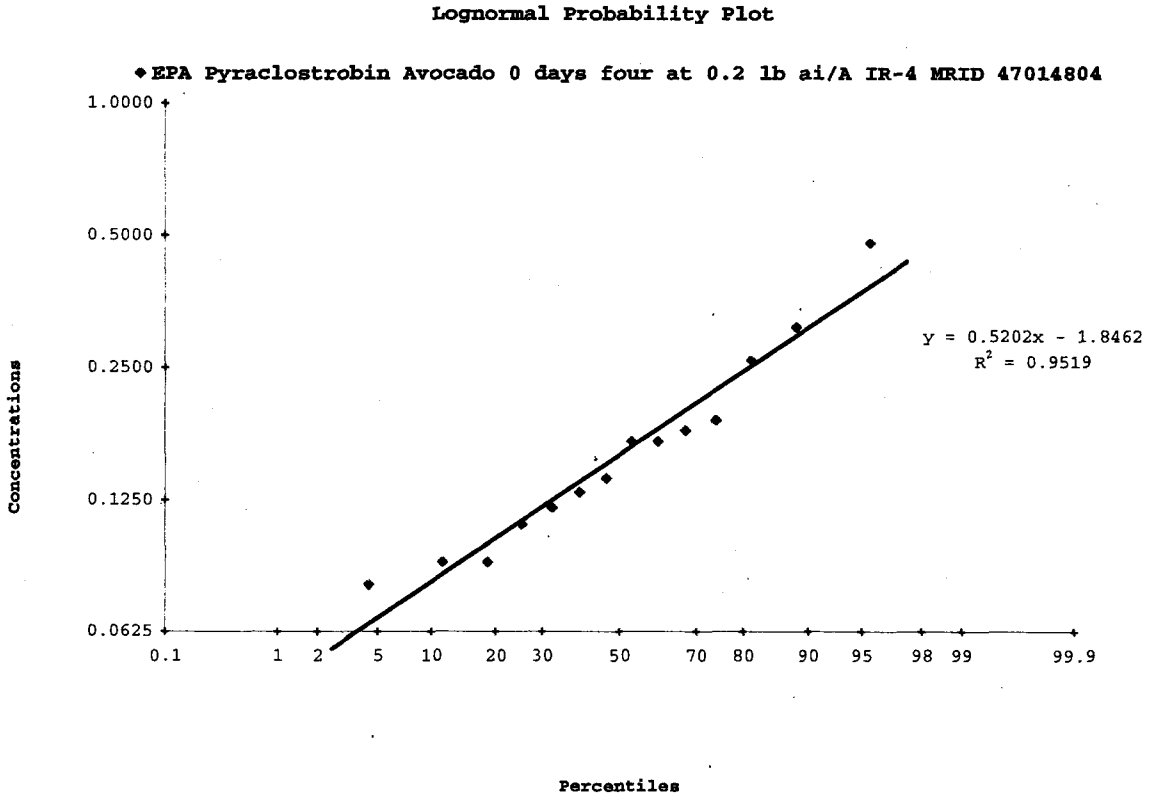


Figure II 4: Data Summary for Residues of Pyraclostrobin in/on Avocado

Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Avocado
PHI:	0 days
App. Rate:	four at 0.2 lb ai/A
Submitter:	IR-4
MRID Citation:	MRID 47014804
n:	14
min:	0.08
max:	0.48
median:	0.16
average:	0.18

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.40 (0.50)	0.45 (0.60)	0.60 (--)
EU Method I Log Normal	0.40 **(0.60)**	**0.60** (1.0)	0.80 (--)
EU Method II Distribution-Free	0.45		
California Method μ + 3σ	**0.60**		
UPLMedian95th	**1.1**		
Approximate Shapiro-Francia Normality Test	0.9519 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Table II-3: Data Used to Calculate Tolerance for Pyraclostrobin in/on Oat Commodities			
Regulator:	EPA		
Chemical:	Pyraclostrobin		
Crop Commodity:	**Oat Grain**	**Oat Straw**	**Oat Hay**
PHI:	20-26 days	20-26 days	6-8 days
App. Rate:	2 x 0.15 lb ai/A/application		
Submitter:	BASF Corporation		
MRID Citation:	MRID 46902226		
	Combined Residues	**Combined Residues**	**Combined Residues**
	0.75	3.34	8.47
	0.43	3.13	2.38
	0.11	3.35	3.81
	0.5	11.9	14.83
	0.12	2.84	7.13
	0.17	5.9	2.52
	0.1	1.33	4.64
	0.45	3.62	5.57
	0.15	4.29	8.67
	0.33	2.97	6.41
	0.34	5.53	6.15
	0.44	4.69	3.69
	0.53	3.3	8.07
	0.4	2.84	2.59
	0.55	4.06	3.5
	0.54	14.9	14.09
	0.13	1.99	3.72
	0.17	4.52	5.85
	0.11	1.76	5.59
	0.42	4.38	7.5
	0.19	5.76	8.4
	0.24	3.78	6.51
	0.35	7.69	6.38
	0.44	4.94	3.56

Figure II 5: Lognormal Probability Plot of Pyraclostrobin in/on Oat Grain

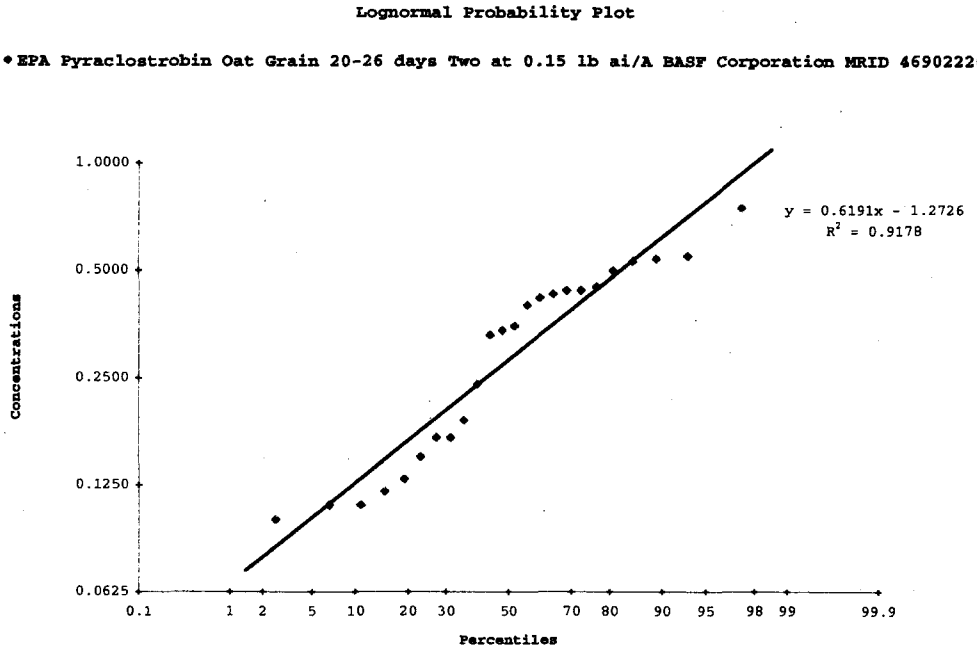


Figure II 6: Data Summary for Residues of Pyraclostrobin in/on Oat Grain

	Regulator: EPA **Chemical:** Pyraclostrobin **Crop:** Oat Grain **PHI:** 20-26 days **App. Rate:** Two at 0.15 lb ai/A **Submitter:** BASF Corporation **MRID Citation:** MRID 46902226 **n:** 24 **min:** 0.10 **max:** 0.75 **median;** 0.35 **average:** 0.33		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	0.70 (0.80)	0.80 (1.0)	0.90 (--)
EU Method I Log Normal	0.80 **(1.2)**	**1.3** (2.5)	2.0 (--)
EU Method II Distribution-Free	0.90		
California Method μ + 3σ	**0.90**		
UPLMedian95th	**2.5**		
Approximate Shapiro-Francia Normality Test	0.9178 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Figure II 7: Lognormal Probability Plot of Pyraclostrobin in/on Oat Straw

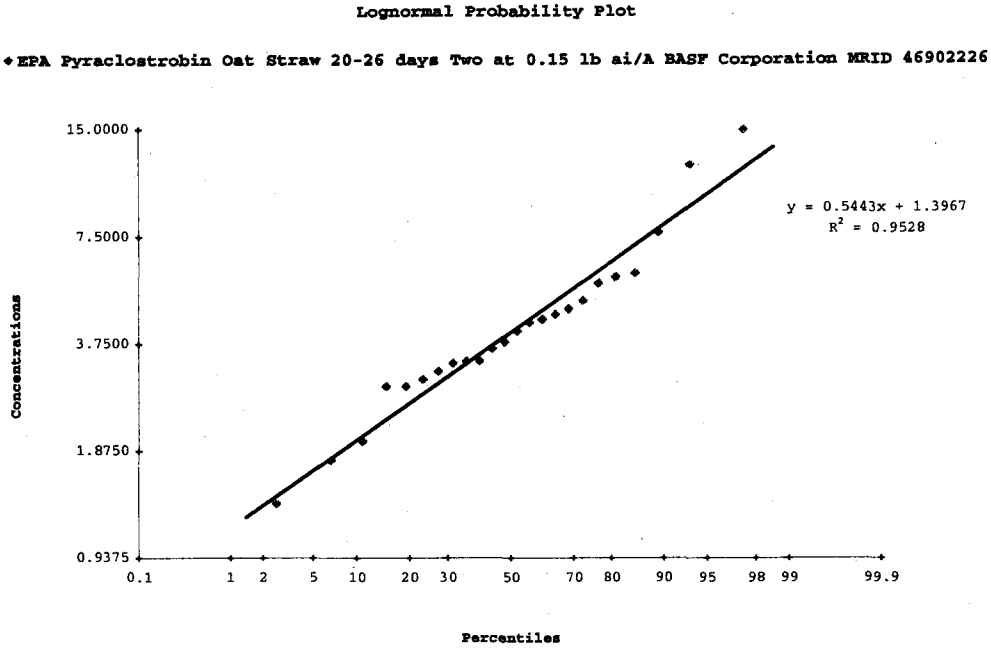


Figure II 8: Data Summary for Residues of Pyraclostrobin in/on Oat Straw.

Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Oat Straw
PHI:	20-26 days
App. Rate:	Two at 0.15 lb ai/A
Submitter:	BASF Corporation
MRID Citation:	MRID 46902226
n:	24
min:	1.33
max:	14.90
median;	3.92
average:	4.70

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	10 (12)	12 (15)	15 (--)
EU Method I Log Normal	10 **(15)**	**15** (25)	25 (--)
EU Method II Distribution-Free		11	
California Method $\mu + 3\sigma$		**14**	
UPLMedian95th		**25**	
Approximate Shapiro-Francia Normality Test		0.9528 p-value > 0.05 : Do not reject lognormality assumption	

Would you like the above values rounded? (Y or N)==> Y

Figure II 9: Lognormal Probability Plot of Pyraclostrobin in/on Oat Hay

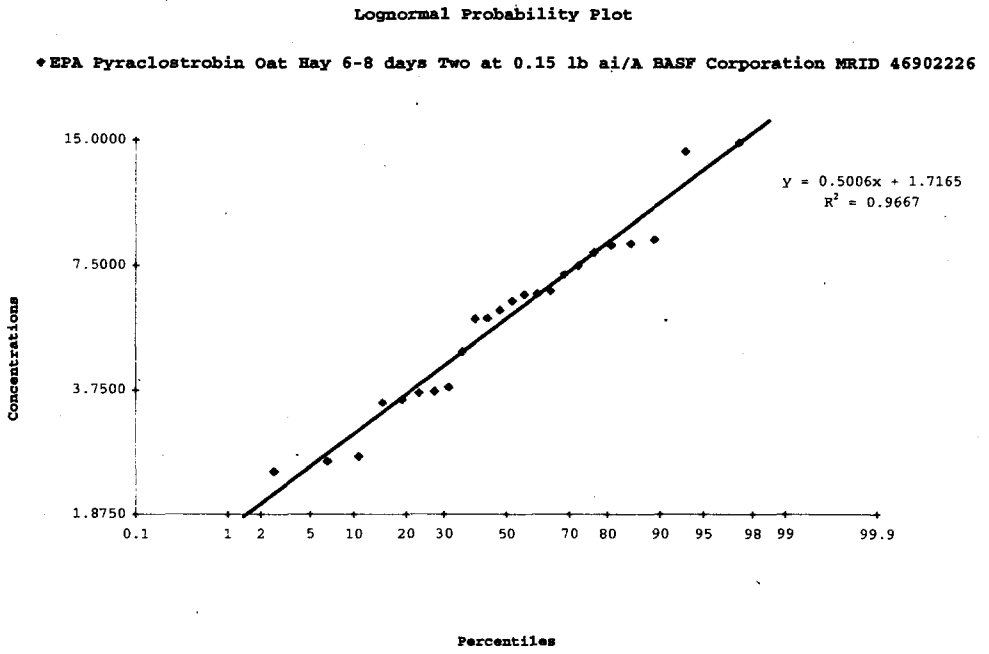


Figure II 10: Data Summary for Residues of Pyraclostrobin in/on Oat Hay.

	Regulator: EPA **Chemical:** Pyraclostrobin **Crop:** Oat Hay **PHI:** 6-8 days **App. Rate:** Two at 0.15 lb ai/A **Submitter:** BASF Corporation **MRID Citation:** MRID 46902226 **n:** 24 **min:** 2.38 **max:** 14.83 **median;** 6.00 **average:** 6.25		
	95th Percentile	**99th Percentile**	**99.9th Percentile**
EU Method I Normal	12 (14)	14 (17)	17 (--)
EU Method I Log Normal	13 **(18)**	**18** (30)	30 (--)
EU Method II Distribution-Free		16	
California Method μ + 3σ		**16**	
UPLMedian95th		**40**	
Approximate Shapiro-Francia Normality Test		0.9667 p-value > 0.05 : Do not reject lognormality assumption	

Would you like the above values rounded? (Y or N)==> Y

Table II-4; Dataset Used to Calculate Tolerance Level for Pyraclostrobin on Barley		
Regulator:	EPA	
Chemical:	Pyraclostrobin	
Crop:	Barley	
PHI:	14-15 days	
App. Rate:	2 x 0.15 lb ai/A/application	
Submitter:	IR-4	
MRID Citation:	MRID 47190501	
	Combined Residues	
	Barley Grain	Barley Straw
	0.81	3.6
	0.82	4.0
	0.54	2.1
	0.56	1.7
	0.88	2.8
	0.98	2.9
	0.87	2.0
	0.92	2.9

Figure II 11: Lognormal Probability Plot of Pyraclostrobin in/on Barley Grain

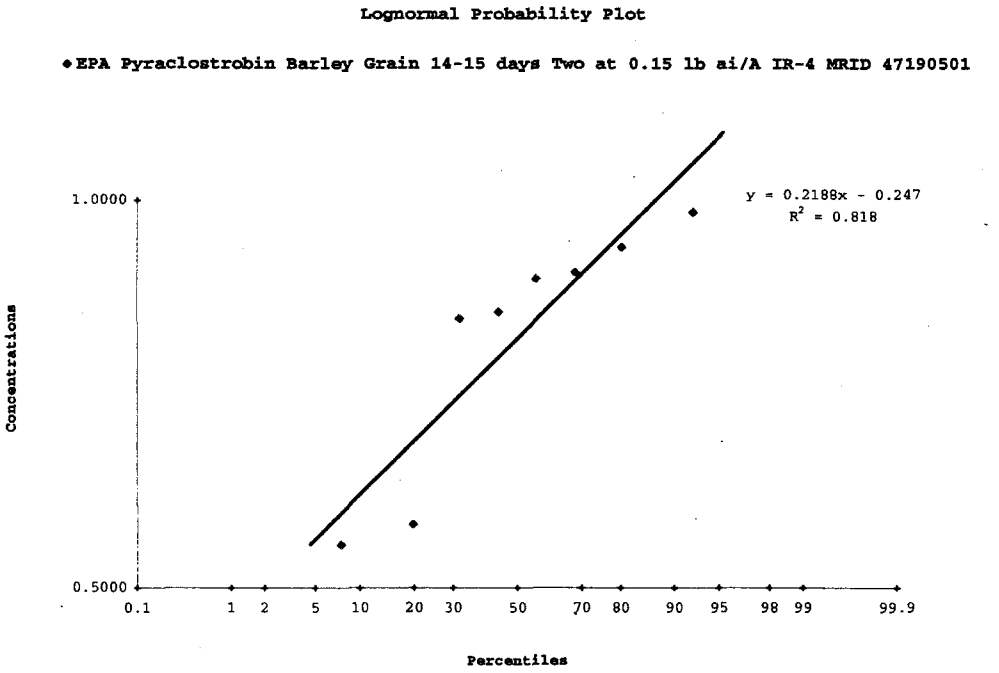


Figure II 12: Data Summary for Residues of Pyraclostrobin in/on Barley Grain.

Table II-4; Dataset Used to Calculate Tolerance Level for Pyraclostrobin on Barley		
Regulator:	EPA	
Chemical:	Pyraclostrobin	
Crop:	Barley	
PHI:	14-15 days	
App. Rate:	2 x 0.15 lb ai/A/application	
Submitter:	IR-4	
MRID Citation:	MRID 47190501	
	Combined Residues	
	Barley Grain	Barley Straw
	0.81	3.6
	0.82	4.0
	0.54	2.1
	0.56	1.7
	0.88	2.8
	0.98	2.9
	0.87	2.0
	0.92	2.9

Figure II 13: Lognormal Probability Plot of Pyraclostrobin in/on Barley Straw

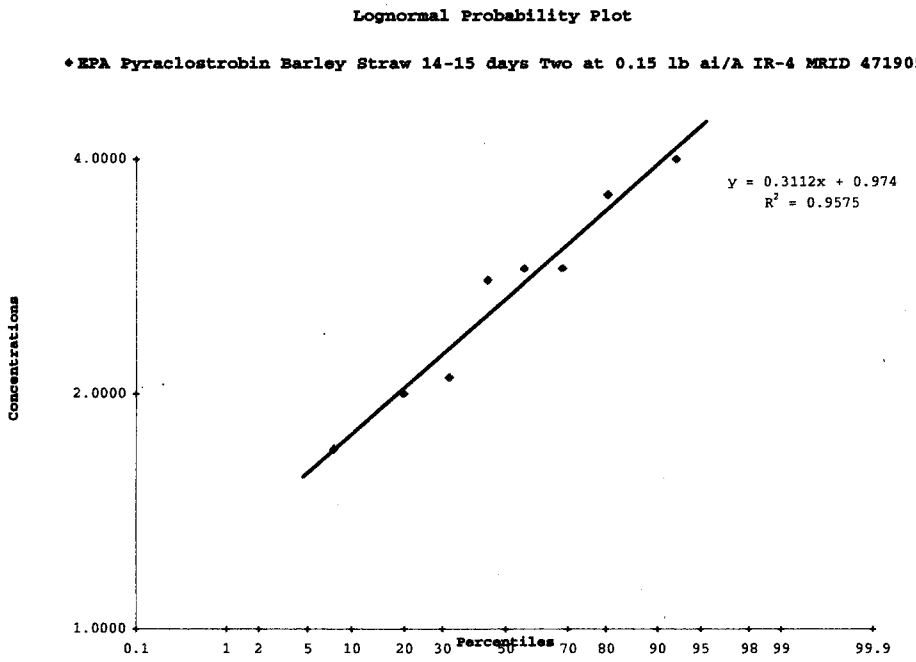


Figure II 14: Data Summary for Residues of Pyraclostrobin in/on Barley Straw.

Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Barley Straw
PHI:	14-15 days
App. Rate:	Two at 0.15 lb ai/A
Submitter:	IR-4
MRID Citation:	MRID 47190501
n:	8
min:	1.70
max:	4.00
median;	2.85
average:	2.75

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	4.5 (6.0)	5.0 (7.0)	6.0 (--)
EU Method I Log Normal	4.5 **(7.0)**	**6.0** (10)	7.0 (--)
EU Method II Distribution-Free	7.0		
California Method $\mu + 3\sigma$	**6.0**		
UPLMedian95th	**30**		
Approximate Shapiro-Francia Normality Test	0.9575 p-value > 0.05 : Do not reject lognormality assumption		

Would you like the above values rounded? (Y or N)==> Y

Table II-5: Data Used to Calculate Tolerance of Pyraclostrobin in/on Canola Seed	
Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Canola Seed (MLE)
PHI:	20-22 days
Application Rate:	2 x 0.19-0.21 lb ai/A/application
Submitter:	BASF Corporation
MRID Citation:	MRID 46925301
	Combined Residues
	0.0086
	0.0117
	0.0142
	0.0166
	0.0188
	0.0500
	0.0210
	0.0232
	0.0600
	0.0500
	0.0254
	0.0277
	0.1300
	0.1100
	0.0300
	0.0323
	0.2200
	0.2700
	0.1300
	0.1600
	0.1300
	0.1200
	0.1900
	0.1500
	0.0500
	0.0500
	0.0500
	0.0500
	0.1000
	0.1200
	0.0348
	0.0373

Figure II 15: Lognormal Probability Plot of Pyraclostrobin in/on Canola Seed

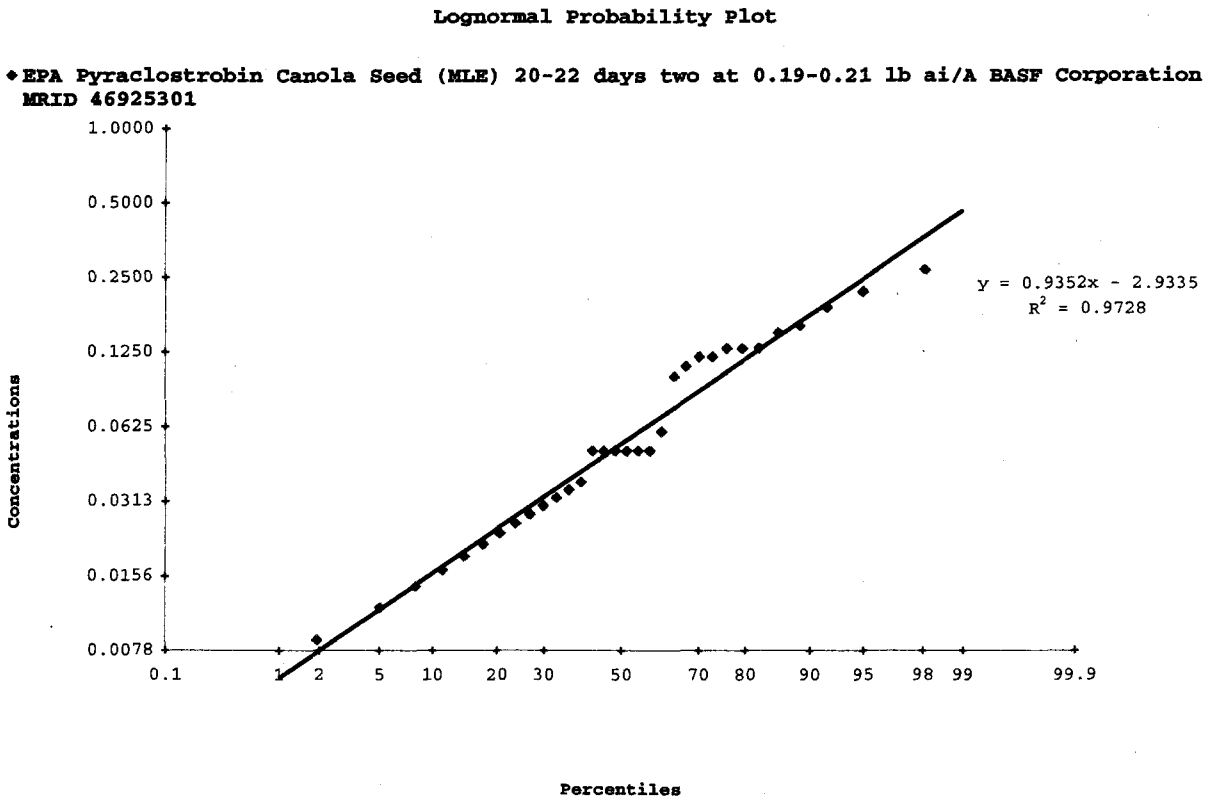


Figure II 16: Data Summary for Residues of Pyraclostrobin in/on Canola Seed

Regulator:	EPA
Chemical:	Pyraclostrobin
Crop:	Canola Seed (MLE)
PHI:	20-22 days
App. Rate:	two at 0.19-0.21 lb ai/A
Submitter:	BASF Corporation
MRID Citation:	MRID 46925301
n:	32
min:	0.01
max:	0.27
median;	0.05
average:	0.08

	95th Percentile	99th Percentile	99.9th Percentile
EU Method I Normal	0.20 (0.25)	0.25 (0.30)	0.30 (--)
EU Method I Log Normal	0.25 **(0.45)**	**0.50** (0.90)	1.0 (--)
EU Method II Distribution-Free		0.30	
California Method $\mu + 3\sigma$		**0.30**	
UPLMedian95th		**0.30**	
Approximate Shapiro-Francia Normality Test		0.9728 p-value > 0.05 : Do not reject lognormality assumption	

Would you like the above values
rounded? (Y or N)==> Y

Pyraclostrobin/BAS 500 F/PC Code 099100/IR-4
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Barley

Primary Evaluator	Jerry B. Stokes, Chemist Reregistration Branch 4 Health Effects Division	Date: 03/03/08
Approved by	Susan V. Hummel, Senior Scientist Reregistration Branch 4 Health Effects Division	Date: 3/4/08

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 10/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47190501. Corley, J. (2007). Pyraclostrobin: Magnitude of the Residue on Barley. Lab Project Number: 09089.04-BAR01. Unpublished study prepared by IR-4. 193 pages.

EXECUTIVE SUMMARY:

IR-4 has submitted field trial data for pyraclostrobin on barley. Four field trials were conducted during the 2004 and 2005 growing season in NAFTA Growing Zones 8 (CO, 2 trials) and 11 (ID, 2 trials). The 2.0 lb/gal EC formulation of pyraclostrobin was applied at each test location as two broadcast foliar sprays at 0.143-0.152 lb ai/A/application, with RTIs of 11-14 days, for totals of 0.29-0.30 lb ai/A. All applications were made using ground equipment (29-37 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of barley grain and straw samples were harvested at 14-15 DAT and 21-23 DAT. No samples of hay were collected. Samples were stored frozen for up to 9.6 months prior to analysis, an interval supported by available storage stability data.

Samples of harvested barley commodities (grain and straw) were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.004 ppm.

The results show that following two spray applications of an EC formulation of pyraclostrobin totaling 0.29-0.30 lb ai/A, combined residues at 14-15 DAT were 0.54-0.98 ppm in/on grain and 1.7-4.0 ppm in/on straw. Combined residues at 21-23 DAT were 0.11-0.49 ppm in/on grain and 0.65-2.2 ppm in/on straw. The HAFT combined residues for grain was 0.93 ppm and for straw was 3.8 ppm at 14-15 DAT, and HAFT combined residues for grain was 0.45 ppm and for straw was 1.8 ppm at 21-23 DAT. The average combined residues at 14-15 DAT were 0.80 ppm for grain and 2.7 ppm for straw, and at 21-23 DAT average combined residues were 0.39 ppm for

grain and 1.4 ppm for straw. The data show that residues of pyraclostrobin in barley commodities were higher in the 14-15 PHI samples than the 21-23 PHI samples.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the submitted field trial data for barley grain and straw are adequate. However, no data were submitted for barley hay. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 343754.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance, which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*.

BASF has submitted field trial data to support label amendment for Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin, to add new foliar uses on oats, canola, flax, and barley. In addition, the petitioner wishes to register BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation, for seed treatment of canola and flax. The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

TABLE A.1. Pyraclostrobin Nomenclature.

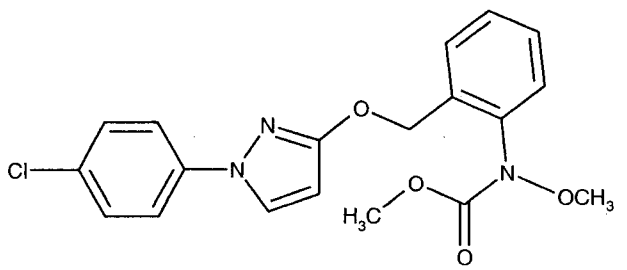
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F

TABLE A.1. Pyraclostrobin Nomenclature.	
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin; BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/g)
Fort Collins, CO 2004	Clay Loam	2.4	7.8	Not reported (NR)
Kimberly, ID 2004	Silt Loam	1.72	8.3	NR
Wellington, CO 2005	Sandy Clay Loam	1.8	7.6	16-18
Kimberly, ID 2005	Silt Loam	1.44	8.2	15.1

54

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information; No Tank Mix/Adjuvants Used				
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)
Fort Collins, CO 2004 CO10	2 lb/gal EC	Two broadcast foliar applications at soft dough to early hard dough	30	0.145-0.148	13	0.293
		Two broadcast foliar applications at watering ripe to soft dough	29-30	0.143-0.145	14	0.288
Kimberly, ID 2004 ID05	2 lb/gal EC	Two broadcast foliar applications at headed to maturing	35-37	0.145-0.151	14	0.296
		Two broadcast foliar applications at heading to seed filling	35	0.144-0.145	14	0.289
Wellington, CO 2005 CO03	2 lb/gal EC	Two broadcast foliar applications at late milk to Zadock 8.7-8.9	31	0.151-0.152	12	0.303
		Two broadcast foliar applications at Zadock 65 to soft dough stage	30-31	0.147-0.151	13	0.298
Kimberly, ID 2005 ID02	2 lb/gal EC	Two broadcast foliar applications at heading to maturing	35-36	0.147-0.149	14	0.296
		Two broadcast foliar applications at heading to maturing	35-36	0.145-0.151	11	0.296

[1] RTI = Retreatment interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Barley		
	Submitted	Requested	
		Canada	US[1]
1			
2			
3			
4			
5			
6			
7			
8	2		2
9			
10			
11	2		2
12			
13			
Total	4	NA	4

[1] This barley petition is for U.S. regional use only (Pacific Northwest and Inner Mountain States; AZ, CO, ID, MT, NV, NM, OR, TX, UT, WA, and WY).

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (amount not reported) of barley grain and straw RAC samples were harvested at 14-15 DAT and 21-23 DAT. Samples were stored frozen (-20°C) ≤30 minutes after collection. Samples were shipped frozen 14-21 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). The samples from one field trial (CO10) had to be redirected to BASF after being shipped to the wrong laboratory. Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of barley grain and straw were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500 3 are expressed as pyraclostrobin equivalents. For each analyte, the validated method LOQ is 0.02 ppm, and the reported LOD is 0.004 ppm.

The adequacy of Method D9908 was verified by fortifying control samples of barley commodities with pyraclostrobin and BF 500-3 at 0.02-10 ppm.

C. RESULTS AND DISCUSSION

In a total of 4 field trials conducted during the 2004-2005 growing season, pyraclostrobin (2 lb/gal EC) was applied to barley as two broadcast foliar sprays at 0.143-0.152 lb ai/A/application, with RTIs of 11-14 days, for totals of 0.29-0.30 lb ai/A. All applications were made using ground equipment (29-37 gal/A of spray volume) and did not include the use of a spray adjuvant. Single control and duplicate treated samples of barley grain and straw samples were harvested at 14-15 DAT and 21-23 DAT.

Barley grain and straw samples were stored frozen for a maximum duration of 9.6 months prior to analysis. Adequate storage stability data are available indicating that pyraclostrobin and metabolite BF 500-3 are relatively stable at ≤-10°C in fortified samples of grape juice (juices), sugar beet tops (leafy vegetables), sugar beet roots (root crop), tomatoes (fruit/fruiting vegetable), and wheat grain (non-oily grain) and wheat straw (dry feed) for up to 25 months, and in fortified samples of peanut nutmeats (oilseed) and peanut oil for up to 19 months (D269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on barley grain and straw was adequately validated in conjunction with the field trial. Concurrent recoveries of pyraclostrobin averaged 103% with a standard deviation of 10%

from grain and 105% with a standard deviation of 6% from straw. Recoveries of BF 500-3 averaged 97% with a standard deviation of 5% from grain and 95% with a standard deviation of 9% from straw (see Table C.1). Apparent residues were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results show that following two spray applications of an EC formulation of pyraclostrobin totaling 0.29-0.30 lb ai/A, combined residues at 14-15 DAT were 0.54-0.98 ppm in/on grain and 1.7-4.0 ppm in/on straw. Combined residues at 21-23 DAT were 0.11-0.49 ppm in/on grain and 0.65-2.2 ppm in/on straw (see Table C.3). The HAFT combined residues for grain was 0.93 ppm and for straw was 3.8 ppm at 14-15 DAT, and HAFT combined residues for grain was 0.45 ppm and for straw was 1.8 ppm at 21-23 DAT. The average combined residues at 14-15 DAT were 0.80 ppm for grain and 2.7 ppm for straw, and at 21-23 DAT average combined residues were 0.39 ppm for grain and 1.4 ppm for straw (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Barley.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ± standard deviation (%)
Pyraclostrobin				
Grain	0.02	4	108, 114, 92, 92	102 ± 11
	1	2	113, 114	114 ± 1
	10	2	92, 102	97 ± 7
	Total	**8**	**92-114**	**103 ± 10**
Straw	0.02	4	99, 102, 106, 109	104 ± 4
	10	4	110, 114, 103, 97	106 ± 8
	Total	**8**	**97-114**	**105± 6**
BF 500-3				
Grain	0.02	4	93, 99, 90, 100	96 ± 5
	1	2	97, 105	101 ± 6
	10	2	94, 99	97 ± 4
	Total	**8**	**93-105**	**97 ± 5**
Straw	0.02	4	80, 84, 96, 99	90 ± 9
	10	4	101, 108, 98, 96	101 ± 5
	Total	**8**	**80-108**	**95 ± 9**

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration (months)	Interval of Demonstrated Storage Stability (months)
Grain Straw	-10	2.7-9.6	19-25 [1]

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Barley Field Trials with Pyraclostrobin.

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Residues (ppm)[1]		
						Pyraclostrobin	BF 500-3	Combined
Fort Collins, CO 2004 CO10	8	Moravian 14	0.29	Grain	15	0.50, 0.50	0.31, 0.32	0.81, 0.82
				Straw	15	2.7, 3.0	0.87, 1.0	3.6, 4.0
			0.29	Grain	21	0.22, 0.23	0.16, 0.15	0.38, 0.38
				Straw	21	1.5, 0.95	0.68, 0.48	2.2, 1.4
Kimberly, ID 2004 ID05	11	812 Winter	0.30	Grain	14	0.38, 0.39	0.16, 0.17	0.54, 0.56
				Straw	14	1.5, 1.3	0.61, 0.42	2.1, 1.7
			0.29	Grain	21	0.08, 0.07	0.04, 0.04	0.12, 0.11
				Straw	21	0.47, 0.47	0.19, 0.18	0.66, 0.65
Wellington, CO 2005 CO03	8	Moravian 37	0.30	Grain	15	0.57, 0.62	0.31, 0.36	0.88, 0.98
				Straw	15	2.2, 2.3	0.56, 0.55	2.8, 2.9
			0.30	Grain	22	0.25, 0.23	0.18, 0.17	0.43, 0.40
				Straw	22	1.1, 1.2	0.31, 0.31	1.4, 1.5
Kimberly, ID 2005 ID02	11	812 Winter	0.30	Grain	14	0.52, 0.56	0.35, 0.36	0.87, 0.92
				Straw	14	1.5, 2.1	0.47, 0.77	2.0, 2.9
			0.30	Grain	23	0.28, 0.23	0.21, 0.18	0.49, 0.41
				Straw	23	0.98, 0.75	0.42, 0.26	1.4, 1.0

[1] For each analyte, the validated method LOQ is 0.02 ppm, and the reported LOD is 0.004 ppm

TABLE C.4. Summary of Residue Data from Barley Field Trials with Pyraclostrobin

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Grain	0.29-0.30	14-15	8	0.54	0.98	0.93	0.85	0.80	0.16
Straw			8	1.7	4.0	3.8	2.8	2.7	0.79
Grain	0.29-0.30	21-23	8	0.11	0.49	0.45	0.39	0.34	0.14
Straw			8	0.65	2.2	1.8	1.4	1.3	0.50

D. CONCLUSION

The barley field trial data are adequate for barley grain and straw. The petitioner did not provide residue data or propose a tolerance for barley hay because applications are made after the growth stages at which barley hay is harvested. The conducted field trials reflect the regional use of EC formulation of pyraclostrobin as two broadcast foliar sprays at ~0.15 lb ai/A/application (without the use of a spray adjuvant) for a total seasonal rate of ~0.3 lb ai/A. The data support a minimum RTI of 14 days, and a 14-day PHI for grain and straw.

E. REFERENCES

DP#s:	269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject:	PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From:	L. Cheng
To:	C. Giles-Parker/J. Bazuin
Dated:	11/28/01
MRIDs:	45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: SHummel (12/10/07)
Petition Number: 7E7245
DP #: 343754
PC Code: 099100

Template Version June 2005

Primary Evaluator	Jerry B. Stokes, Chemist Reregistration Branch 4 Health Effects Division	Date: 03/03/08
Approved by	Susan V. Hummel, Senior Scientist Reregistration Branch 4 Health Effects Division	Date: 3/3/08

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

MRID# 46902226. Jordan, J.M (2006). The Magnitude of Metconazole (BAS 555F) and its Metabolites and Pyraclostrobin (BAS 500 F) Residues in Oats. BASF Reg. Doc. No. 2006/7006724. BASF Study Number 137717. Unpublished study prepared by BASF Corporation. 119 Pages.

EXECUTIVE SUMMARY:

BASF Corporation has submitted field trial data for pyraclostrobin on oats. Twelve field trials were conducted during the 2004 and 2005 growing season: eleven spring oat trials in NAFTA Growing Zones 1 (NY, 1 trial), 5 (IL, ND, WI, 1 trial each), 5B (QB, 1 trial), 6 (OK, 1 trial), 7 (ND and NE, 1 trial each), and 14 (AB, MB, and SK, 1 trial each); and one winter oat trial in Zone 2 (GA, 1 trial). The test formulation used in all trials was BAS 500 02F (2.0 lb/gal EC). BAS 500 02F was applied at each test location as two broadcast sprays at 0.14-0.16 lb ai/A/application, with a 6-8 day retreatment interval, for a total rate of 0.29-0.31 lb ai/A. Applications were initiated approximately 4 weeks prior to the harvest of mature grain or approximately 2 weeks prior to the cutting of hay. Applications were made using ground equipment (10-27 gal/A of spray volume) and included the use of an adjuvant as well as a tank mixture with another active ingredient (metconazole); only the residue data from application of pyraclostrobin are reported in this Data Evaluation Record.

Single control and duplicate treated samples of oat hay were harvested from each test site at 6-8 days after the last treatment (DAT). Grain and straw samples were harvested at 20-21 DAT. Grain and straw samples from the OK trial site were collected at 26 DAT due to adverse weather conditions that prevented harvest at the target PHI. At one site, hay samples were harvested at 0, 7, and 14 DAT, and grain/straw samples were harvested at 14, 21, 28 and 36 DAT to generate residue decline data. Samples were stored frozen for up to 12.4 months prior to analysis, an interval supported by available storage stability data.

Samples of harvested oat commodities were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.01 ppm.

The results show that following two spray applications of BAS 500 02F (EC formulation) totaling 0.29-0.31 lb ai/A, combined residues ranged 0.10-0.75 ppm in/on grain (n = 24 samples) and 1.33-14.90 ppm in/on straw (n = 24 samples) at 20-26 DAT. Combined residues were 2.38-14.83 ppm in/on hay (n = 24 samples) at 6-8 DAT. The highest average field trial (HAFT) combined residues were 0.64 ppm for grain, 13.40 ppm for straw, and 14.46 ppm for hay. The average combined residues were 0.33 ppm for grain, 4.70 ppm for straw, and 6.25 ppm for hay. The residue decline data show that residues of pyraclostrobin remain relatively constant in oat commodities with increasing preharvest intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the oat field trial data are classified as inadequate because no residue data were submitted for oat forage. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 334535.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*.

BASF has submitted field trial data to support label amendment for Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin, to add new foliar uses on oats, canola, and flax. In addition, the petitioner

wishes to register BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation, for seed treatment of canola and flax. The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

TABLE A.1. Pyraclostrobin Nomenclature.

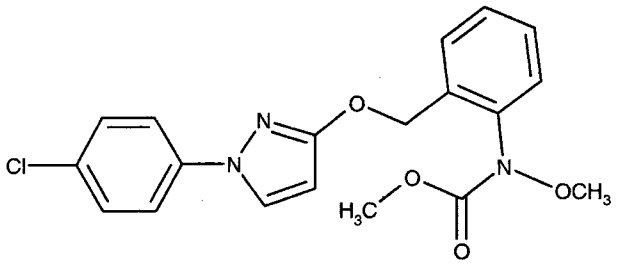
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin; BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.			
Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.				
Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/g)
Wayne, NY 2005	Silt Loam	4.1	5.0	Not reported (NR)
Tift, GA 2004	Loamy Sand	1	5.5	NR
Clinton, IL 2005	Silt Loam	2.3	7.0	NR
Pepin, WI 2005	Sandy Loam	2.9	5.7	NR
Stutsman, ND 2005	Sandy Loam	4.7	5.7	NR
Hall, NE 2005	Clay Loam	2.7	6.6	NR
Cass, ND 2005	Loam	4.1	8.2	NR
Caddo, OK 2005	Sandy Loam	NR	NR	NR
St-Cesaire, QB 2005	Loamy Sand	4.1	4.7	NR
Rosthern, SK 2005	Loam	7.2	7.0	NR
Minto, MB 2005	Loam	4.9	7.5	NR
Innisfail, AB 2005	Clay Loam	7.6	6.2	NR

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Wayne, NY 2005 26	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	24-25	0.14-0.15	8	0.29	Induce
		Two broadcast foliar applications ~2 weeks prior to hay cutting	25	0.15	7	0.30	
Tift, GA 2004 27	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	14-15	0.15-0.16	7	0.30	Penetron
		Two broadcast foliar applications ~2 weeks prior to hay cutting	17-18	0.15	8	0.30	
Clinton, IL 2005 28	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	17	0.15	7	0.30	NIS
		Two broadcast foliar applications ~2 weeks prior to hay cutting	12-18	0.15	8	0.30	
Pepin, WI 2005 29	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	20	0.15	7	0.30	Induce
		Two broadcast foliar applications ~2 weeks prior to hay cutting	20	0.15	7	0.30	
Stutsman, ND 2005 30	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	15-20	0.15	7	0.30	Activator 90
		Two broadcast foliar applications ~2 weeks prior to hay cutting	10-12	0.15	8	0.31	
Hall, NE 2005 31	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	20	0.15	7	0.30	Activate Plus
		Two broadcast foliar applications ~2 weeks prior to hay cutting	20	0.15	7	0.30	
Cass, ND 2005 32	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	16	0.15	6	0.30	Activator 90
		Two broadcast foliar applications ~2 weeks prior to hay cutting	16-17	0.15	7	0.31	
Caddo, OK 2005 33	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	13-14	0.15	7	0.30	Baron
		Two broadcast foliar applications ~2 weeks prior to hay cutting	13-14	0.15	7	0.30	
St-Cesaire, QB 2005 34	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	22-24	0.14-0.15	7	0.29	Surf 92
		Two broadcast foliar applications ~2 weeks prior to hay cutting	24-25	0.15-0.16	7	0.31	
Rosthern, SK 2005 35	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	21-22	0.15	8	0.30	Ag Surf
		Two broadcast foliar applications ~2 weeks prior to hay cutting	21-22	0.15	7	0.30	
Minto, MB 2005 36	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	21-22	0.15	7	0.30	Ag Surf
		Two broadcast foliar applications ~2 weeks prior to hay cutting	22	0.15	6	0.30	
Innisfail, AB 2005 37	2 lb/gal EC	Two broadcast foliar applications ~ 4 weeks prior to grain harvest	24-25	0.15	7	0.30	Merge
		Two broadcast foliar applications ~2 weeks prior to hay cutting	24-27	0.15	7	0.29	

[1] RTI = Retreatment interval.

63

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Oat		
	Submitted	Requested	
		Canada	US[1]
1	1	1	1
2	1		1
3			
4			
5	1	1	9
5A		1	
5B	1	1	
6	1		1
7	2		3
8			1
9			
10			
11			
12			
13			
14	3	10	
Total	12	16	16

[1] The field trials listed in the column indicate the trials required to established individual tolerances (not as part of a crop group tolerance) for oat RACs.

Geographic representation of data is not in full compliance with GLN 860.1500 requirements since only 12 trials were conducted; the guideline requires a total of 16 trials to establish individual tolerances for oat commodities. However, the petitioner has included Appendix J in the study report which documents correspondence between EPA and BASF regarding the "Proposal to EPA and PMRA for Reduction of the Number of Field Residue Sites Required to Set a Fungicide Tolerance in Small Grains (Wheat, Barley, Oats, and Rye)". Based on the total number of field trials conducted for small grains, it was reported that the conducted trials for oats should be adequate to set individual tolerances on wheat, barley, oats, and rye.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (amount not reported) of oat hay were collected from each test at 6-8 DAT, and grain and straw RAC samples were harvested at 20-21 DAT, with the exception of one trial where the grain and straw were collected at 26 DAT due to adverse conditions that prevented harvest. At one site hay samples were harvested at 0, 7, and 14 DAT, and grain and straw samples were harvested at 14, 21, 28, and 36 DAT to examine residue decline. Samples were stored frozen promptly (time not reported) after collection. Samples were shipped frozen 2-52 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of oat hay, grain and straw were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500 3 are expressed as pyraclostrobin equivalents. For each analyte, the validated method LOQ is 0.02 ppm, and the reported LOD is 0.01 ppm.

The adequacy of Method D9908 was verified by fortifying control samples of oat commodities with pyraclostrobin and BF 500-3 at 0.02 and 4.0 ppm.

C. RESULTS AND DISCUSSION

In a total of 12 field trials conducted during the 2004-2005 growing season, pyraclostrobin (2 lb/gal EC) was applied to oats as two broadcast foliar sprays at 0.14-0.16 lb ai/A/application, with RTIs of 6-8 days, for totals of 0.29-0.31 lb ai/A. All applications were made using ground equipment (10-27 gal/A of spray volume) and included the use of a spray adjuvant. Single control and duplicate treated samples of oat hay samples were harvested from each test site at 6-8 days after treatment (DAT), and grain and straw samples were harvested at 20-21 DAT, with the exception of one trial where grain and straw were collected at 26 DAT due to adverse weather that prevented harvest. At one site, hay samples were harvested at 0, 7 and 14 DAT, and grain/straw samples were harvested at 14, 21, 28 and 36 DAT to examine residue decline.

Oat hay, grain and straw samples were stored frozen for maximum durations of 12.4, 11.3 and 11.4 months, respectively, prior to analysis. Adequate storage stability data are available indicating that pyraclostrobin and metabolite BF 500-3 are relatively stable at $\leq$-10°C in fortified samples of grape juice (juices), sugar beet tops (leafy vegetables), sugar beet roots (root crop), tomatoes (fruit/fruiting vegetable), and wheat grain (non-oily grain) and wheat straw (dry feed) for up to 25 months, and in fortified samples of peanut nutmeats (oilseed) and peanut oil for up to 19 months (D269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on oat hay, grain and straw was adequately validated in conjunction with the field trial. Concurrent recoveries of pyraclostrobin averaged 83% with a standard deviation of 11% from hay, 97% with a standard deviation of4% from grain and 93% with a standard deviation of 11% from straw. Recoveries of BF 500-3 averaged 85% with a standard deviation of 12% from hay, 83% with a standard deviation of 11% from grain, and 92% with a standard deviation of 4% from straw (see Table C.1). Apparent residues were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples of grain, but did not bracket residues found in straw and hay.

The results show that following two spray applications of an EC formulation of pyraclostrobin totaling 0.29-0.31 lb ai/A, combined residues at 20-26 DAT were 0.10-0.75 ppm in/on grain and 1.33-14.90 ppm in/on straw. Combined residues at 6-8 DAT were 2.38-14.83 ppm in/on hay (see Table C.3). The HAFT combined residues for grain was 0.64 ppm, for straw 13.40 ppm, and for hay 14.46 ppm. The average combined residues were 0.33 ppm, 4.70 ppm and 6.35 ppm, respectively (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Oat.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Hay	0.02	3	87, 100, 76	88 ± 12
	4.0	2	71, 79	75± 6
	Total	**5**	**71-100**	**83± 11**
Grain	0.02	2	102, 96	99± 4
	4.0	2	92, 99	96± 5
	Total	**4**	**92-102**	**97 ± 4**
Straw	0.02	2	100, 91	96 ± 6
	4.0	2	78, 102	90±17
	Total	**4**	**78-102**	**93± 11**
BF 500-3				
Hay	0.02	3	86, 89, 92	89 ± 3
	4.0	2	64, 93	79 ± 21
	Total	**5**	**64-93**	**85 ±12**
Grain	0.02	2	87, 75	81 ±8
	4.0	2	96, 73	85 ± 16
	Total	**4**	**73-96**	**83 ± 11**
Straw	0.02	2	89, 91	90 ± 1
	4.0	2	91, 98	95 ± 5
	Total	**4**	**89-98**	**92 ± 4**

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (months)	Interval of Demonstrated Storage Stability (months)
Hay	-10	7.6-12.4	19-25 [1]
Grain		7.2-11.3	
Straw		7.0-11.4	

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Oat Field Trials with Pyraclostrobin.

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Residues (ppm)		
						Pyraclostrobin	BF 500-3	Combined
Wayne, NY 2005 26	1	AC Alymer (winter)	0.29	Grain	20	0.59, 0.43	0.16, 0.10	0.75, 0.53
				Straw	20	2.66, 2.58	0.68, 0.72	3.34, 3.30
			0.30	Hay	7	6.81, 6.70	1.66, 1.37	8.47, 8.07
Tift, GA 2004 27	2	Horizon 314 (Spring)	0.30	Grain	21	0.33, 0.31	0.09, 0.09	0.43, 0.40
				Straw	21	2.33, 2.14	0.80, 0.70	3.13, 2.84
			0.30	Hay	7	2.00, 2.12	0.40, 0.48	2.40, 2.60
Clinton, IL 2005 28	5	Seed oats (Spring)	0.30	Grain	21	0.08, 0.40	0.03, 0.15	0.11, 0.55
				Straw	21	2.63, 3.23	0.72, 0.83	3.35, 4.06
			0.30	Hay	7	2.91, 2.92	0.90, 0.58	3.81, 3.50
Pepin, WI 2005 29	5	Vista (Spring)	0.30	Grain	20	0.36, 0.40	0.13, 0.14	0.50, 0.54
				Straw	20	8.93, 11.08	2.97, 3.83	11.90, 14.90
			0.30	Hay	7	12.96, 12.38	1.87, 1.71	14.83, 14.09
Stutsman, ND 2005 30	7	Morton (Spring)	0.30	Grain	21	0.10, 0.11	0.02, 0.03	0.12, 0.13
				Straw	21	2.32, 1.65	0.51, 0.33	2.84, 1.99
			0.31	Hay	8	6.04, 3.14	1.09, 0.57	7.13, 3.72
Hall, NE 2005 31	7	Jerry (Spring)	0.30	Grain	21	0.13, 0.14	0.04, 0.03	0.17, 0.17
				Straw	21	4.76, 3.69	1.14, 0.83	5.90, 4.52
			0.30	Hay	6	2.07, 4.40	0.45, 1.14	2.52, 5.85
Cass, ND 2005 32	5	Morton (Spring)	0.30	Grain	14	0.12, 0.13	0.04, 0.04	0.16, 0.17
					21	0.08, 0.09	<0.02, <0.02	0.10, 0.11
					28	0.12, 0.10	0.03, 0.02	0.15, 0.12
					36	0.15, 0.11	0.05, 0.04	0.20, 0.15
				Straw	14	2.83, 2.99	0.53, 0.43	3.36, 3.42
					21	1.15, 1.53	0.17, 0.23	1.33, 1.76
					28	2.72, 2.98	0.51, 0.63	3.22, 3.60
					36	2.87, 2.10	0.55, 0.45	3.42, 2.55
			0.31	Hay	0	18.57, 17.24	1.46, 1.32	20.3, 18.56
					7	4.07, 4.86	0.54, 0.73	4.64, 5.59
					14	2.39, 2.29	0.39, 0.42	2.77, 2.71
Caddo, OK 2005 33	6	Jerry (Spring)	0.30	Grain	26	0.33, 0.31	0.12, 0.11	0.45, 0.42
				Straw	26	2.82, 3.57	0.80, 0.81	3.62, 4.38
			0.30	Hay	6	4.62, 6.11	0.95, 1.39	5.57, 7.50
St-Cesaire, QB 2005 34	5B	Rigodon (Spring)	0.29	Grain	21	<0.02, <0.02	0.13, 0.17	0.15, 0.19
				Straw	21	3.61, 5.02	0.68, 0.74	4.29, 5.76
			0.31	Hay	7	7.67, 7.38	1.00, 1.02	8.67, 8.40
Rosthern, SK 2005 35	14	Furlong (Spring)	0.30	Grain	20	0.26, 0.17	0.07, 0.06	0.33, 0.24
				Straw	20	2.59, 3.19	0.37, 0.59	2.97, 3.78
			0.30	Hay	7	5.23, 5.31	1.18, 1.20	6.41, 6.51
Minto, MB 2005 36	14	Triple Crown (Spring)	0.30	Grain	20	0.29, 0.30	0.05, 0.05	0.34, 0.35
				Straw	20	4.64, 6.62	0.90, 1.07	5.53, 7.69
			0.30	Hay	7	5.17, 5.50	0.99, 0.89	6.15, 6.38
Innisfail, AB 2005 37	14	AC LU (Spring)	0.30	Grain	21	0.36, 0.35	0.09, 0.09	0.44, 0.44
				Straw	21	3.80, 4.06	0.90, 0.88	4.69, 4.94
			0.29	Hay	7	2.68, 2.93	1.07, 0.63	3.69, 3.56

TABLE C.4. Summary of Residue Data from Oat Field Trials with Pyraclostrobin									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Combined Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Grain	0.29-0.31	20-26	24	0.10	0.75	0.64	0.35	0.33	0.18
Straw			24	1.33	14.90	13.40	3.92	4.70	3.07
Hay	0.29-0.31	6-8	24	2.38	14.83	14.46	6.00	6.25	3.20

D. CONCLUSION

The oat field trial data are adequate and support the use of EC formulation of pyraclostrobin as two broadcast foliar spray at ~0.15 lb ai/A/application for a total seasonal rate of ~0.3 lb ai/A. The data support a minimum RTI of 6 days, and a 6-8-day PHI for hay and a 20-26-day PHI for grain and straw. The petitioner did not provide residue data or propose a tolerance for oat forage because applications are made after the growth stages at which oat is foraged.

E. REFERENCES

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From: L. Cheng
To: C. Giles-Parker/J. Bazuin
Dated: 11/28/01
MRIDs: 45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: SHummel (12/10/07)
Petition Number: 6E7105
DP #: 334535
PC Code: 099100

Template Version June 2005

Primary Evaluator	Jerry B. Stokes, Chemist Reregistration Branch 4 Health Effects Division	Date: 03/03/08
Approved by	Susan V. Hummel, Senior Scientist Reregistration Branch 4 Health Effects Division Susan V Hummel	Date: 3/4/08

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46925301. Jordan, J.M (2006). The Magnitude of Pyraclostrobin (BAS 500 F) Residues in Canola and Canola Processed Fractions. BASF Reg. Doc. No. 2006/7006722. BASF Study Number 137471. Unpublished study prepared by BASF Corporation. 119. Pages.

EXECUTIVE SUMMARY:

BASF Corporation has submitted field trial data for pyraclostrobin on canola. Sixteen field trials were conducted during the 2005 growing season in NAFTA Growing Zones 5 (ND and SD, 1 trial each), 7 (ND, 1 trial), 11 (ID, 1 trial), and 14 (AB, 4 trials; SK, 5 trials; and MB, 3 trials). In each trial site, the 2.0 lb/gal EC formulation of pyraclostrobin was applied to established canola plants during pod development as two broadcast foliar sprays at 0.19-0.21 lb ai/A/application, with a 6-7 day retreatment interval, for a total rate of 0.39-0.41 lb ai/A. At five locations, a separate treatment plot received two foliar broadcast sprays at 0.1 lb ai/A/application for a total rate of 0.20 lb ai/A. The latter treatment was included to provide bridging residue data for oilseed crops for which the maximum use rate may be lower than the proposed rate for canola. Applications were made using ground equipment (20-31 gal/A of spray volume) and included the use of an adjuvant. Single control and duplicate treated samples of canola seeds were harvested from each test site 20-22 days after the second treatment (DAT). At two sites treated with the higher rate, canola seed samples were collected at 0, 10, 21-22, 30, and 39-41 DAT to generate residue decline data. Samples were stored frozen for up to 7.6 months prior to analysis, an interval supported by available storage stability data.

Samples of harvested canola seeds were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.005 ppm.

The results show that following two applications of the 2.0 lb/gal EC formulation of

pyraclostrobin reflecting PHI of 20-22 days, combined residues in/on canola seed were <0.04-0.27 ppm for samples (n = 32) treated at a total rate of 0.39-041 lb ai/A and were <0.04-0.11 ppm for samples (n = 10) treated at a total rate of 0.20 lb ai/A. The average combined residues were 0.08 and 0.06 ppm in/on samples treated at high and low rates, respectively. The residue decline data indicate that residues of pyraclostrobin decrease at longer preharvest intervals.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the canola field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 334535.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*.

BASF has submitted field trial data to support label amendment for Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin, to add new foliar uses on oats, canola, and flax. In addition, the petitioner wishes to register BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation, for seed treatment of canola and flax. The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

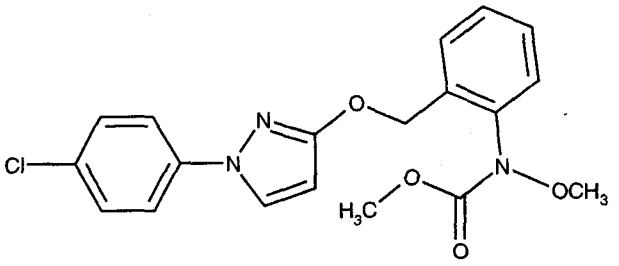
TABLE A.1. Pyraclostrobin Nomenclature.	
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin; BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

11

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	%OM	pH	CEC (meq/g)
Marshall, SD 2005	Clay Loam	3.8	7.7	Not reported (NR)
Cass, ND 2005	Loam	4.1	8.2	NR
Stutsman, ND 2005	Sandy Loam	4.7	5.7	NR
Payette, ID 2005	Silty Clay Loam	0.65	6.2	NR
Minto MB 2005	Loam	4.9	7.5	NR
Rosthern, SK 2005	Loam	7.2	7.0	NR
Moissevain, MB 2005	Loam	4.6	7.4	NR
Hepburn, SK 2005	Loam	4.6	7.5	NR
Laird, SK 2005	Fine Silty Loam	5.6	5.8	NR
Innisfail, AB 2005	Clay Loam	7.6	6.2	NR
Innisfail, AB 2005	Loam	5.6	6.5	NR
Fort SK, AB 2005	Silty Clay Loam	7	6.3	NR
Fort SK, AB 2005	Loam	6.4	7.1	NR
Alvena, SK 2005	Loam	2.9	7.0	NR
Alvena, SK 2005	Loam	2.9	7.0	NR
Brookdale, MB 2005	Loam	5.1	6.3	NR

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Marshall, SD 2005 24	2.0 lb/gal EC	Two broadcast foliar applications during pod development	20	0.20	7	0.40	Yes
Cass, ND 2005 25	2.0 lb/gal EC	Two broadcast foliar applications during pod development	20	0.20	6	0.40	Activator 90
Stutsman, ND 2005 26	2.0 lb/gal EC	Two broadcast foliar applications during pod development	20-21	0.20-0.21	7	0.41	Yes
Payette, ID 2005 27	2.0 lb/gal EC	Two broadcast foliar applications during pod development	31	0.20	7	0.41	Preference
Minto MB 2005 28	2.0 lb/gal EC	Two broadcast foliar applications during pod development	22	0.20	6	0.40	Ag-Surf
Rosthern, SK 2005 29	2.0 lb/gal EC	Two broadcast foliar applications during pod development	22	0.20	6	0.40	Ag-surf
Moissevain, MB 2005 30	2.0 lb/gal EC	Two broadcast foliar applications during pod development	23-24	0.20-0.21	7	0.41	Ag-surf
Hepburn, SK 2005 31	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21-22	0.20	6	0.40	Yes
Laird, SK 2005 32	2.0 lb/gal EC	Two broadcast foliar applications during pod development	22	0.20	6	0.40	Ag-surf
Innisfail, AB 2005 34	2.0 lb/gal EC	Two broadcast foliar applications during pod development	30	0.21	7	0.41	Ag-surf
Innisfail, AB 2005 34	2.0 lb/gal EC	Two broadcast foliar applications during pod development	30-31	0.20	7	0.40	Ag-surf
Fort SK, AB 2005 35	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21-22	0.20	7	0.40	Yes
			21-22	0.10	7	0.20	
Fort SK, AB 2005 36	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21-22	0.20-0.21	7	0.40	Yes
			21-22	0.10	7	0.20	
Alvena, SK 2005 37	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21-22	0.20	6	0.40	Yes
			21-22	0.10	6	0.20	
Alvena, SK 2005 38	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21-22	0.20	6	0.40	Yes
			21-22	0.10	6	0.20	
Brookdale, MB 2005 39	2.0 lb/gal EC	Two broadcast foliar applications during pod development	21	0.19-0.20	7	0.39	Second application only
			21-22	0.10	7	0.20	

[1] RTI = Retreatment interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Canola		
	Submitted	Requested	
		Canada	US
1			
2			2
3			
4			
5	2	1	2
6			
7	1	1	2
8			
9			
10			
11	1		3
12			
13			
14	12	14	
Total	16	16	8

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (≥2.2 lb) of canola seeds were collected from each test location at 20-22 DAT. Fresh samples were stored frozen promptly (time not reported) after collection. Samples were shipped frozen 3-40 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of canola seed were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500 3 are expressed as pyraclostrobin equivalents. For each analyte, the validated method LOQ is 0.02 ppm, and the reported LOD is 0.005 ppm.

The adequacy of Method D9908 was verified by fortifying control samples of canola seed with pyraclostrobin and BF 500-3 at 0.02 to 2.0 ppm.

74

C. RESULTS AND DISCUSSION

In a total of sixteen field trials conducted during the 2005 growing season, the 2.0 lb/gal EC formulation of pyraclostrobin was applied to growing canola plants as two broadcast foliar sprays at 0.19-0.21 lb/application ai/A for totals of 0.39-0.41 lb ai/A. All applications were made during pod development, with RTIs of 6-7 days, using ground equipment at 20-31 gal/A, and included the use of a spray adjuvant. At five locations, a separate treatment plot received two broadcast foliar sprays at 0.10 lb ai/A/application for a total rate of 0.20 lb ai/A. This treatment was included to provide bridging residue data for oilseed crops for which the maximum use rate may be lower than the rate for canola. Applications were made in 21-22 gal/A of water and included the use of a spray adjuvant. Single control and duplicate treated samples of canola seeds were harvested from each test site 20-22 days after the final treatment (20-22 DAT). At two sites treated with the higher application rate, canola was harvested at 0, 10, 21-22, 30, and 39-41 DAT to examine residue decline.

Canola seed samples were stored frozen for up to 9 months prior to analysis. Adequate storage stability data are available indicating that pyraclostrobin and metabolite BF 500-3 are relatively stable at ≤-10 °C in fortified samples of grape juice (juices), sugar beet tops (leafy vegetables), sugar beet roots (root crop), tomatoes (fruit/fruiting vegetable), and wheat grain (non-oily grain) and wheat straw (dry feed) for up to 25 months, and in fortified samples of peanut nutmeats (oilseed) and peanut oil for up to 19 months (D269668, L. Cheung, 11/28/01).
The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on canola seed was adequately validated in conjunction with the field trials. Concurrent recoveries of pyraclostrobin averaged 105% with a standard deviation of 8%, and the average recovery of BF 500-3 was 99% with a standard deviation of 6% (see Table C.1). Apparent residues of pyraclostrobin were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in/on treated samples.

The results show that following two applications of pyraclostrobin totaling 0.39-0.41 lb ai/A, combined residues at 20-22 DAT were <0.04-0.27 ppm with an average of 0.08 ppm. Combined residues following applications totaling 0.20 lb ai/A were <0.04-0.11 ppm with and an average of 0.06 ppm (see Table C.3). The HAFT following the higher application was 0.25 ppm, and the HAFT for the lower application was 0.10 ppm. (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Canola.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Canola Seed	0.02	2	103, 117	110
	2.0	2	99, 103	101
	Total	**4**	**99-117**	**105 ± 8**
BF 500-3				
Canola Seed	0.02	2	108, 98	103
	2.0	2	94, 96	95
	Total	**4**	**94-108**	**99±6**

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (months)	Interval of Demonstrated Storage Stability (months)
Canola Seed	-10	5.8-7.6	19-25 [1]

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Canola Field Trials with Pyraclostrobin.

Location (City, State; Year) Trial ID	Zone	Variety	Commodity	Total Rate (lb ai/A)	PHI (days)	Residues (ppm)		
						Pyraclostrobin	B 500-3	Combined
Marshall, SD 2005 24	5	HYOLA 357 RR	Seed	0.40	22	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Cass, ND 2005 25	5	Clearfield	Seed	0.40	0	0.05, 0.02	<0.02, <0.02	0.07, 0.04
					10	0.03, <0.02	<0.02, <0.02	0.05, <0.04
					22	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
					30	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
					39	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Stutsman, ND 2005 26	7	46A76	Seed	0.41	22	<0.02, 0.03	<0.02, <0.02	<0.04, 0.05
Payette, ID 2005 27	11	Hyola 308	Seed	0.41	21	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Minto MB 2005 28	14	RR 34-65	Seed	0.40	0	0.38, 0.17	0.08, 0.04	0.46, 0.21
					10	0.09, 0.05	0.03, 0.02	0.12, 0.07
					21	0.04, 0.03	<0.02, <0.02	0.06, 0.05
					30	<0.02, 0.03	<0.02, <0.02	<0.04, 0.05
					41	0.03, <0.02	<0.02, <0.02	0.05, <0.04
Rosthern, SK 2005 29	14	SP Banner	Seed	0.40	21	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Moissevain, MB 2005 30	14	DeKalb 34-55	Seed	0.41	22	0.08, 0.07	0.05, 0.04	0.13, 0.11
Hepburn, SK 2005 31	14	Clearfield	Seed	0.40	21	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Laird, SK 2005 32	14	289 CL	Seed	0.40	21	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Innisfail, AB 2005 33	14	Advanta 110	Seed	0.41	21	0.18, 0.22	0.04, 0.05	0.22, 0.27

TABLE C.3. Residue Data from Canola Field Trials with Pyraclostrobin.

Location (City, State; Year) Trial ID	Zone	Variety	Commodity	Total Rate (lb ai/A)	PHI (days)	Residues (ppm)		
						Pyraclostrobin	B 500-3	Combined
Innisfail, AB 2005 34	14	1862	Seed	0.40	21	0.09, 0.10	0.04, 0.06	0.13, 0.16
Fort SK, AB 2005 35	14	SP Banner	Seed	0.40	20	0.10, 0.10	0.03, 0.02	0.13, 0.12
				0.20	20	0.05, 0.06	<0.02, <0.02	0.07, 0.08
Fort SK, AB 2005 36	14	SP 451 RR	Seed	0.40	20	0.16, 0.12	0.03, 0.03	0.19, 0.15
				0.20	20	0.07, 0.08	<0.02, 0.03	0.09, 0.11
Alvena, SK 2005 37	14	SP Banner	Seed	0.40	22	0.03, 0.04	<0.02, <0.02	0.05, 0.05
				0.20	22	0.02, <0.02	<0.02, <0.02	0.04, <0.04
Alvena, SK 2005 38	14	SP 451 RR	Seed	0.40	22	0.03, 0.03	<0.02, <0.02	0.05, 0.05
				0.20	22	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04
Brookdale, MB 2005 39	14	Roundup Ready	Seed	0.39	21	0.05, 0.06	0.05, 0.06	0.10, 0.12
				0.20	22	<0.02, <0.02	<0.02, <0.02	<0.04, <0.04

TABLE C.4. Summary of Combined Residue Data from Canola Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A) [1]	PHI (days)	Combined Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Canola Seed	0.39-0.41	20-22	32	<0.04	0.27	0.25	0.05	0.08	0.06
	0.20	21-22	10	<0.04	0.11	0.10	0.04	0.06	0.03

D. CONCLUSION

The field trial data are adequate and support the use of the 2.0 lb/gal EC formulation of pyraclostrobin on canola as two broadcast foliar applications during pod development at ~0.20 lb ai/A/application for a total seasonal rate of ~0.40 lb ai/A. The data support a minimum RTI of 7 days and a 21-day PHI.

E. REFERENCES

DP#s:	269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject:	PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From:	L. Cheng
To:	C. Giles-Parker/J. Bazuin
Dated:	11/28/01
MRIDs:	45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: SHummel (12/10/07)
Petition Number: 6E7105
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Pyraclostrobin/BAS 500 F/PC Code 099100/BASF Corporation
DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIIA 8.5
Processed Food and Feed - Canola

Primary Evaluator	Jerry B. Stokes, Chemist Reregistration Branch 4 Health Effects Division	Date: 03/03/08
Approved by	Susan V. Hummel, Senior Scientist Reregistration Branch 4 Health Effects Division	Date: 3/4/08

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 07/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

46925301. Jordan, J.M (2006). The Magnitude of Pyraclostrobin (BAS 500 F) Residues in Canola and Canola Processed Fractions. BASF Reg. Doc. No. 2006/7006722. BASF Study Number 137471. Unpublished study prepared by BASF Corporation. 119. Pages.

EXECUTIVE SUMMARY:

BASF Corporation has submitted a processing study with pyraclostrobin on canola. Samples used for processing were generated from a field trial conducted during the 2005 growing season in Saskatchewan, Canada. The 2.0 lb/gal EC formulation of pyraclostrobin was applied to established canola plants during pod development as two broadcast foliar sprays at 0.6 lb ai/A/application, with a 6-day retreatment interval, for a total rate of 1.2 lb ai/A (4.0x the field trial application rate). Applications were made using ground equipment (22 gal/A of spray volume) and included the use of an adjuvant. Single control and duplicate treated samples of canola seeds were harvested from the test site 21 days after the final spray treatment. The harvested canola bulk seed samples were frozen immediately and shipped to a processing facility where they were processed into meal and refined oil using simulated commercial procedures. Canola seed, meal, and refined oil samples were stored frozen for up to 3.3, 2.5, and 1.8 months, respectively, prior to residue analysis. The storage conditions and durations of samples are supported by available storage stability data.

Samples of canola seed and its processed commodities were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. For each analyte, the validated method limit of quantitation (LOQ) is 0.02 ppm, and the reported limit of detection (LOD) is 0.005 ppm.

The results indicate that the combined residues of pyraclostrobin and its metabolite BF 500-3 averaged 0.05 ppm in/on canola seed treated at a total rate of 1.2 lb ai/A. Following processing, combined residues were <0.04 ppm in meal and 0.06 ppm in refined oil. The equivalent processing factors from these data are 0.8x for meal and 1.2x for refined oil. The maximum theoretical concentration factors for canola processed commodities, based on separation into components, are 1.9x for meal and 3.0x for oil (OPPTS GLN 860.1520, Table 3).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the canola processing data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 334535.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*.

BASF has submitted field trial data to support label amendment for Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin, to add new foliar uses on oats, canola, and flax. In addition, the petitioner wishes to register BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation, for seed treatment of canola and flax. The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

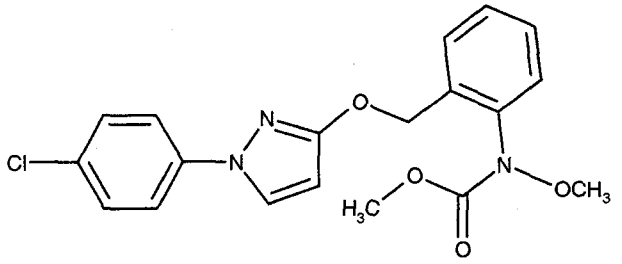
TABLE A.1. Pyraclostrobin Nomenclature.	
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	Headline® Fungicide (EPA Reg. No. 7969-186), an EC formulation containing 23.6% ai (2.09 lb/gal) pyraclostrobin; BAS 500 ST (EPA File Symbol 7969-EUN), a 20% WDG formulation

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.			
Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

B. EXPERIMENTAL DESIGN

B.1. Application and Crop Information

TABLE B.1.1. Study Use Pattern

Location (County, State; Year) Trial ID	End-use Product	Application					Tank Mix/ Adjuvants
		Method; Timing	Volume (gal/A)	Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Rosthern, SK 2005 29	2.0 lb/gal EC	Two broadcast foliar applications during pod development	22	0.60	6	1.2	Ag-Surf

[1] RTI = Retreatment interval

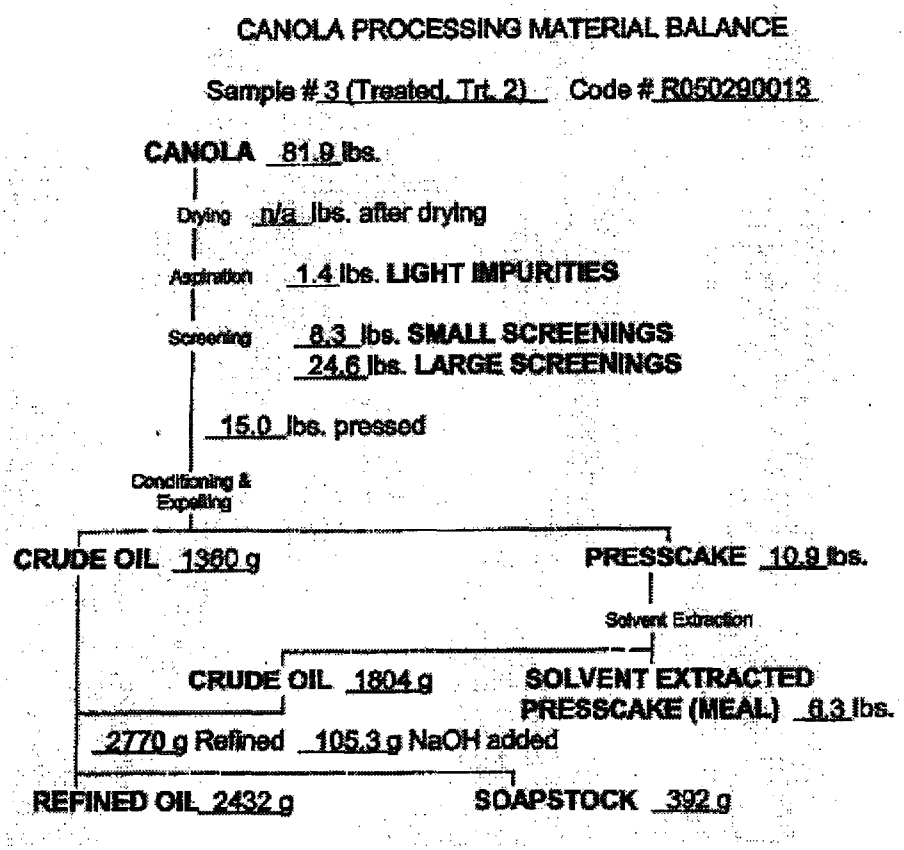
B.2. Sample Handling and Processing Procedures

Bulk control and treated seed samples were harvested at 21 DAT and frozen immediately after collection. Samples were shipped frozen 36 days after harvest by ACDS Freezer truck to a processing facility, GLP Technologies (Navatosa, TX). Samples were received frozen and were placed in frozen storage prior to processing, which was completed within 14 days of sample receipt.

Bulk samples were processed into canola meal and refined oil according to simulated commercial procedures; see Figure 1. Seeds were flaked in a flaking roll and heated at 180-120 °F for 10-15 minutes and pressed in an expeller to mechanically remove crude oil. The residual oil remaining was repeatedly extracted using hexane at 120-140 °F. The extracted meal was then desolventized using warm air or by heating to 200-210 °F. The crude oil and hexane mixture was separated, and the crude oil was heated to 163-194 °F for hexane removal.

Processing samples were placed in frozen storage immediately after processing. Samples were shipped 3 days after completion of processing by overnight courier on dry ice to the analytical laboratory, BASF Agro Research (RTP, NC).

FIGURE 1. Processing Flowchart for Canola.



B.3. Analytical Methodology

Samples of canola seed, meal, and refined oil were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500 3 are expressed as pyraclostrobin equivalents. For each analyte, the validated method LOQ is 0.02 ppm, and the reported LOD is 0.005 ppm.

The adequacy of Method D9908 was verified by fortifying control samples of canola seed with pyraclostrobin and BF 500-3 at 0.02 to 2.0 ppm.

83

C. RESULTS AND DISCUSSION

Canola seed, meal, and refined oil samples were stored frozen for up to 3.3, 2.5, and 1.8 months, respectively, prior to residue analysis. Adequate storage stability data are available indicating that pyraclostrobin and metabolite BF 500-3 are relatively stable at ≤-10 °C in fortified samples of grape juice (juices), sugar beet tops (leafy vegetables), sugar beet roots (root crop), tomatoes (fruit/fruiting vegetable), and wheat grain (non-oily grain) and wheat straw (dry feed) for up to 25 months, and in fortified samples of peanut nutmeats (oilseed) and peanut oil for up to 19 months (D269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on canola seed, meal and refined oil was adequately validated in conjunction with the field trial. Concurrent recoveries of pyraclostrobin from seed averaged 105% with a standard deviation of 8%, and the average recovery of BF 500-3 was 99% with a standard deviation of 6% Concurrent recoveries of pyraclostrobin averaged 81% for canola meal and 78% for canola oil. Recoveries of BF 500-3 averaged 84% for canola meal and 73% for canola oil (see Table C.1). Apparent residues of pyraclostrobin were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results of the processing study indicate that following application of pyraclostrobin to canola totaling 1.2 lb ai/A, combined residues of pyraclostrobin and its metabolite BF 500-3 averaged 0.05 ppm in canola seed, <0.04 ppm in canola meal, and 0.06 ppm in refined oil. Based on these data, the calculated processing factors are 0.8x for meal and 1.2x for refined oil (see Table C.3).

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin and BF 500-3 from Canola Processed Products.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean ∀ std dev (%)
Pyraclostrobin				
Canola Meal	0.02	1	85	81
	2	1	77	
Canola Oil	0.02	1	82	78
	2	1	74	
Canola Seed	0.02	2	103, 117	110
	2.0	2	99, 103	101
	Total	**4**	**99-117**	**105 ± 8**
BF 500-3				
Canola Meal	0.02	1	89	84
	2	1	79	
Canola Oil	0.02	1	81	73
	2	1	64	
Canola Seed	0.02	2	108, 98	103
	2.0	2	94, 96	95
	Total	**4**	**94-108**	**99±6**

84

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration (Months)	Interval of Demonstrated Storage Stability (Months)
Canola see	-10	3.3	19-25 [1]
Meal		2.5	
Refined oil		1.8	

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Canola Processing Study with Pyraclostrobin.							
RAC	Processed Commodity	Total Rate (lb ai/A)	PHI (days)	Combined Residues of Pyraclostrobin and its BF 500-3 Metabolite (ppm)			Processing Factor
				Pyraclostrobin	BF-500-3	Combined	
Canola seed	Seed	1.2	21	0.02, 0.03	<0.02, <0.02	<0.04, 0.05	--
	Meal			<0.02, 0.03	<0.02, <0.02	<0.04, <0.04	0.8
	Refined oil			0.04, 0.04	0.02, 0.03	0.05, 0.07	1.2

D. CONCLUSION

The canola processing study is adequate. The study resulted in processing factors of 0.8x and 1.2x for canola meal and refined oil, respectively.

E. REFERENCES

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From: L. Cheng
To: C. Giles-Parker/J. Bazuin
Dated: 11/28/01
MRIDs: 45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: SHummel (12/10/07)
Petition Number: 6E7105
DP #: 334535
PC Code: 099100

Template Version June 2005

Pyraclostrobin/BAS 500 F/PC Code 099100/IR-4
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Avocado

Secondary Evaluator	Bonnie Cropp-Kohlligian, Environmental Scientist Reregistration Branch 4 Health Effects Division (7509P)	Date: October 1, 2007
Approved by	Susan V. Hummel, Senior Scientist Reregistration Branch 4 Health Effects Division (7509P)	Date: October 1, 2007

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47014804. Carpenter, D.H. (2006) BAS 516: Magnitude of the Residue on Avocado. Lab Project Number: 08446.02-BAR01. Unpublished study prepared by IR-4. 203 pages.

EXECUTIVE SUMMARY:

IR-4 has submitted field trial data for pyraclostrobin on avocados. Seven field trials were conducted in NAFTA Growing Zones 10 (CA, 4 trials) and 3 (FL, 3 trials) during the 2002 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to established avocado trees as four directed foliar sprays at 0.18-0.20 lb ai/A/application for a total seasonal rate of 0.73-0.78 lb ai/A. Applications were made at the fruiting stage and repeated on a 6- to 8-day retreatment interval using ground equipment (152-176 gal/A of spray volume) and did not include the use of a spray adjuvant. Applications included a tank mixture with another active ingredient (boscalid, formulated as BAS 510 UCF); only the residue data from treatments with pyraclostrobin are reported in this Data Evaluation Record.

Single control and duplicate treated samples of avocado fruits were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 182 days prior to analysis, an interval supported by available storage stability data.

Samples of harvested avocado fruits were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. The adequacy of Method D9908 was verified by fortifying control samples of avocados with pyraclostrobin and BF 500-3 at 0.02 to 5.0 ppm. The Lowest Level of Method Validation (LLMV) was 0.02 ppm for residues of pyraclostrobin and BF 500-3.

The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.73-0.78 lb ai/A, combined residues ranged 0.08-0.48 ppm in/on avocados (n=14 samples) harvested at 0 DAT. The average combined residues in/on treated fruit samples were 0.18 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the avocado field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 336189.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*. IR-4 has submitted field trial data in support label amendment for Pristine® Fungicide (EPA Reg. No.7969-199) to incorporate new uses on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs under Petition Number 6E7165. Pristine® Fungicide is a WDG formulation containing multiple active ingredients of pyraclostrobin (12.8%) and boscalid (25.2%). The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

TABLE A.1. Pyraclostrobin Nomenclature.

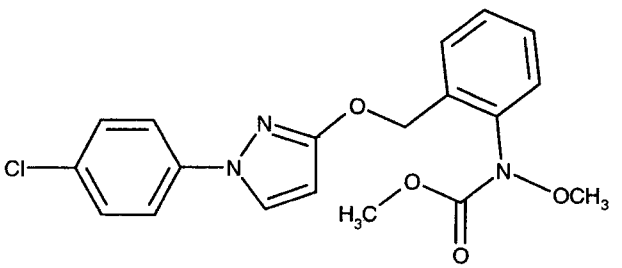
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate

TABLE A.1. Pyraclostrobin Nomenclature.	
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	12.8% WDG (Pristine® Fungicide; EPA Reg. No. 7969-199, which also contains 25.2% of boscalid)

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20 °C	PCF01847: 1998/10768	45118212
Water solubility at 20 °C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20 °C 6.4 x 10^{-10} hPa at 25 °C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/g)
Homestead, FL; 2002	Loam	3-10	7.4-8.4	Not reported (NR)
Homestead, FL; 2002	Loam	3-10	7.4-8.4	NR
Homestead, FL; 2002	Loam	3-10	7.4-8.4	NR
Woodland, CA; 2002	Sandy loam	3.9	7.3	NR
Orosi, CA; 2002	Clay	NR	6.1-8.4	NR
Lindcove, CA; 2002	Loam	NR	6.6-7.8	NR
Nipomo, CA; 2002	Clay	1-3	6.1-8.4	NR

88

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI[1] (days)	Total Rate (lb ai/A)	
Homestead, FL; 2002 FL44	BAS 500 02F	Four directed foliar applications during fruiting	173-176	0.19	6-8	0.77	None
Homestead, FL; 2002 FL45	BAS 500 02F	Four directed foliar applications during fruiting	154-160	0.18-0.19	7	0.75	None
Homestead, FL; 2002 FL46	BAS 500 02F	Four directed foliar applications during fruiting	157-159	0.19	7-8	0.75	None
Woodland, CA; 2002 CA100	BAS 500 02F	Four directed foliar applications during ripening	168-174	0.18	7	0.73	None
Orosi, CA; 2002 CA101	BAS 500 02F	Four directed foliar applications during fruiting	163-168	0.18	6-7	0.74	None
Lindcove, CA; 2002 CA102	BAS 500 02F	Four directed foliar applications during fruiting	152-153	0.18	7	0.73	None
Nipomo, CA; 2002 CA103	BAS 500 02F	Four directed foliar applications during fruiting	161-169	0.19-0.20	6-7	0.78	None

[1] RTI = Retreatment interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Avocado		
	Submitted	Requested	
		Canada	US
1			
2			
3	3[1]		1
4			
5			
6			
7			
8			
9			
10	4		4
11			
12			
13			
Total	7		5

[1] The Region 3 trials were carried out in Homestead Florida, which is close to the boundary line of Regions 3 and 13.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (<4 lbs) of avocados were collected from each test location at 0 DAT. Samples were stored frozen within 4.5 hours of collection and shipped frozen

2-21 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of avocados were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500-3 are expressed as pyraclostrobin equivalents.

The adequacy of Method D9908 was verified by fortifying control samples of avocados with pyraclostrobin and BF 500-3 at 0.02 to 5.0 ppm.

C. RESULTS AND DISCUSSION

In a total of seven field trials conducted during the 2002 growing season, pyraclostrobin (BAS 500 02F) was applied to avocado as four broadcast foliar sprays at 0.18-0.20 lb ai/A/application to fruiting trees at RTIs of 6-8 days, for totals of 0.73-0.78 lb ai/A. All applications were made using ground equipment at 152-176 gal/A, and did not include the use of a spray adjuvant. Single control and duplicate treated samples of mature avocados were harvested from each test location at 0 DAT.

Avocado samples were stored frozen for 182 days prior to analysis. Storage stability data are available indicating that both pyraclostrobin and BF 500-3 are stable in frozen storage for 19-25 months in representative plant matrices (DP# 269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on avocado was adequately validated prior to and in conjunction with the field trial. Method validation recoveries averaged 99% with a standard deviation of 8% for pyraclostrobin, and 95% with a standard deviation of 11% from BF 500-3. Concurrent recoveries averaged 94% with a standard deviation of 13% for pyraclostrobin and 83% with a standard deviation of 17% from BF 500-3 (see Table C.1). The Lowest Level of Method Validation (LLMV) was 0.02 ppm for residues of pyraclostrobin and BF 500-3. Apparent residues were <LLMV (0.02 ppm) in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results of the field trials show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.73-0.78 lb ai/A, combined residues ranged 0.08-0.48 ppm in/on avocados harvested at 0 DAT (see Table C.3). Average combined residues were 0.18 ppm, and the Highest Average Field Trial (HAFT) was 0.40 ppm (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin and BF 500-3 from Avocados.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Method Validation	0.02	3	160[1], 85, 93	89 ±6
	0.50	3	91, 97, 104	97 ±7
	5.0	3	107, 102, 109	106 ±4
	Total	**9**	**85-109**	**99 ±8**
Concurrent Recoveries	0.02	1	98	98
	1.0	2	105, 80	93 ±18
	Total	**3**	**80-105**	**94 ±13**
BF 500-3				
Method Validation	0.02	3	93, 79, 83	85 ±7
	0.50	3	102, 102, 116	107 ±8
	5.0	3	90, 96, 90	92 ±3
	Total	**9**	**79-116**	**95 ±11**
Concurrent Recoveries	0.02	1	64	64
	1.0	2	96, 90	93 ±4
	Total	**3**	**64-96**	**83 ±17**

[1] Rejected by the petitioner as an outlier.

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (days)	Interval of Demonstrated Storage Stability (months)
Avocado	<-10	182	19-25 [1]

[1] DP# 269668, L. Cheung, 11/28/01.

91

TABLE C.3. Residue Data from Avocado Field Trials with Pyraclostrobin.

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	PHI (days)	Residues [1] (ppm)		
					Pyraclostrobin	BF 500-3	Combined
Homestead, FL; 2002 FL44	3	Peterson	0.77	0	0.06, 0.07	<0.02, <0.02	0.08, 0.09
Homestead, FL; 2002 FL45	3	Booth 8	0.75	0	0.10, 0.07	<0.02, <0.02	0.12, 0.09
Homestead, FL; 2002 FL46	3	Peterson	0.75	0	0.09, 0.11	<0.02, <0.02	0.11, 0.13
Woodland, CA; 2002 CA100	10	Zutano	0.73	0	0.24, 0.17	<0.02, <0.02	0.26, 0.19
Orosi, CA; 2002 CA101	10	Hass	0.74	0	0.29, 0.46	<0.02, <0.02	0.31, 0.48
Lindcove, CA; 2002 CA102	10	Bacon	0.73	0	0.16, 0.12	<0.02, <0.02	0.18, 0.14
Nipomo, CA; 2002 CA103	10	Gwen and Bacon	0.78	0	0.15, 0.15	<0.02, <0.02	0.17, 0.17

[1] The Lowest Level of Method Validation (LLMV) for residues of pyraclostrobin and BF 500-3 was 0.02 ppm.

TABLE C.4. Summary of Residue Data from Avocado Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT[1]	Median (STMdR)	Mean (STMR)	Std. Dev.
Avocado	0.73-0.78	0	14	0.08	0.48	0.40	0.16	0.18	0.11

[1] HAFT = Highest Average Field Trial

D. CONCLUSION

The submitted field trial data are adequate and support the use of pyraclostrobin (BAS 500 02F) on avocados as four broadcast foliar sprays at 0.18-0.20 lb ai/A/application during the fruiting stage for a total seasonal rate of 0.73-0.78 lb ai/A. The data support a minimum RTI of 6 days and a 0-day PHI.

E. REFERENCES

DP#s:	269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject:	PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From:	L. Cheng
To:	C. Giles-Parker/J. Bazuin
Dated:	11/28/01
MRIDs:	45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

Petition Number: 6E7165
DP #: 336189
PC Code: 099100

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Pyraclostrobin/BAS 500 F/PC Code 099100/IR-4
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Dill

Primary Evaluator	Gary Otakie, Chemist HED/RRB4 (7509P)	Date: 10/25/07
Approved by	Susan V. Hummel, Branch Senior Scientist HED/RRB4 (7509P)	Date: 10/31/07

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47014801. Carpenter, D.H. (2006) BAS 516: Magnitude of the Residue on Dill. Lab Project Number: 08691. Unpublished study prepared by BASF Corporation. 214 pages.

EXECUTIVE SUMMARY:

IR-4 has submitted field trial data for pyraclostrobin on dill. Four field trials were conducted in NAFTA Growing Zones 2 (MD, 1 trial), 3 (FL, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to dill as four directed foliar sprays at 0.19-0.21 lb ai/A/application for a total seasonal rate of 0.80-0.83 lb ai/A. Applications were made beginning when dill plants were at the vegetative growth stage through seed production; the retreatment intervals were 6 to 8 days. Foliar sprays were made using ground equipment (28-62 gal/A of spray volume) and did not include the use of a spray adjuvant. Applications included a tank mixture with another active ingredient (boscalid, formulated as BAS 510 UCF); only the residue data from treatments with pyraclostrobin are reported in this Data Evaluation Record.

Single control and duplicate treated samples of fresh dill and dill seeds were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 171 days prior to analysis, an interval supported by available storage stability data.

Samples of harvested fresh dill and dill seeds were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. The LOQ and LOD for fresh dill were statistically calculated as 0.023 ppm and 0.008 ppm for pyraclostrobin, and as 0.030 ppm and 0.010 ppm, respectively, for BF 500-3.

The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.80-0.83 lb ai/A, combined residues at 0 DAT ranged 3.98-19.54 ppm in/on 8 samples of fresh dill and 3.60-22.60 ppm in/on 6 samples of dill seed. The average combined residues were 10.46 ppm in/on treated fresh dill and 14.45 ppm in/on treated dill seed.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the dill field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 336189.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*. IR-4 has submitted field trial data in support label amendment for Pristine® Fungicide (EPA Reg. No.7969-199) to incorporate new uses on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs. Pristine® Fungicide is a WDG formulation containing multiple active ingredients of pyraclostrobin (12.8%) and boscalid (25.2%). The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

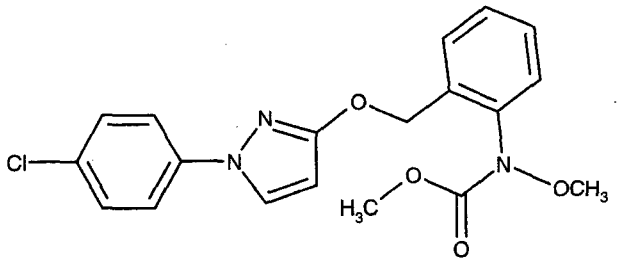
TABLE A.1. Pyraclostrobin Nomenclature.	
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	12.8% WDG (Pristine® Fungicide; EPA Reg. No. 7969-199, which also contains 25.2% of boscalid)

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

96

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	%OM	pH	CEC (meq/g)
Citra, FL 2003	Coarse Sand	1.92-2.04	5.6	Not reported
Salinas, CA 2003	Sandy Loam	2.0	7.2	14
Moxee, CA 2003	Sandy Loam	0.99	6.7	Not reported
Salisbury, MD 2003	Loamy Sand	0.8-0.9	5.8-6.1	Not reported

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Citra, FL 2003 FL54	BAS 500 02F	Four broadcast foliar applications during vegetation	30, 31	0.20	7	0.81	None
		Five broadcast foliar applications during seed development	30	0.20	7-8	1.0	None
Salinas, CA 2003 CA124	BAS 500 02F	Four broadcast foliar applications during vegetation	47, 62	0.20-0.21	6-7	0.82	None
		Four broadcast foliar applications during seed development	42, 43	0.19-0.20	6-7	0.80	None
Moxee, CA 2003 WA17	BAS 500 02F	Four broadcast foliar applications during vegetation	29, 28	0.20-0.21	6-7	0.82	None
		Four broadcast foliar applications during seed development	28, 29	0.20-0.21	7-8	0.83	None
Salisbury, MD 2003 MD23	BAS 500 02F	Four broadcast foliar applications during vegetation	26	0.20	6-8	0.81	None

[1] RTI = Retreatment interval.

97

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Dill		
	Submitted	Requested [1]	
		Canada	US
1			
2	1		
3	1		
4			
5			
6			
7			
8			
9			
10	1		
11	1		
12			
Total	4		3

[1] OPPTS 860.1500 requires three trials with two treated samples at 1X or two trials with four treated samples (two at 1X and two at 2X per trial) but does not specify the geographic locations of the required trials for dill.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples of fresh dill (<2 lbs) and of dried dill seed (<0.5 lb) were collected from each test plot at 0 DAT. Fresh samples were stored frozen within 45 minutes of collection, and seed samples were stored frozen within 80 minutes of collection. Samples were shipped frozen 26-56 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of fresh dill and dill seeds were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500-3 are expressed as pyraclostrobin equivalents. The LOQ and LOD for fresh dill were statistically calculated as 0.023 ppm and 0.008 ppm for pyraclostrobin, and as 0.030 ppm and 0.010 ppm, respectively, for BF 500-3.

The adequacy of Method D9908 was verified by fortifying control samples of fresh dill with pyraclostrobin and BF 500-3 at 0.05 to 40.0 ppm; control samples of dill seed were fortified at 0.05 to 200 ppm.

C. RESULTS AND DISCUSSION

In a total of four field trials conducted during 2003, pyraclostrobin was applied to dill as four directed foliar applications at 0.19-0.21 lb ai/A/application from vegetative development stage through seed production with RTIs of 6-8 days, for totals of 0.80-0.83 lb ai/A. All applications were made using ground equipment at 28-62 gal/A, and did not include the use of a spray adjuvant. At the FL trial, a fifth application was made to the plot designated for seed harvest, as the crop was immature at the time of the fourth application. A total of 1.0 lb ai/A was applied to this FL plot. Single control and duplicate treated samples of fresh dill and dill seed were harvested from each trial site at 0 DAT.

The harvested samples of fresh dill and dill seed were stored frozen for 171 and 147 days, respectively, prior to analysis. Storage stability data are available indicating that both pyraclostrobin and BF 500-3 are stable in frozen storage for 19-25 months in representative plant matrices (DP# 269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on fresh dill and dill seed was adequately validated in conjunction with the field trial. Concurrent recoveries of pyraclostrobin on fresh dill averaged 89% with a standard deviation of 10%, and the average recovery from dill seed was 82% with a standard deviation of 9%. The average recovery of BF 500-3 from fresh dill was 90% with a standard deviation of 11%, and the average recovery from dill seed was 76% with a standard deviation of 9% (see Table C.1). Apparent residues of pyraclostrobin were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results indicate that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.80-0.83 lb ai/A, combined residues at 0 DAT ranged 3.98-19.54 ppm in/on 8 samples of fresh dill and 3.60-22.60 ppm in/on 6 samples of dill seed (see Table C.3). Average combined residues were 10.46 ppm in/on fresh dill and 14.45 ppm in/on dill seed. The HAFT was 19.01 ppm for fresh dill and 21.20 ppm for dill seed (see Table C.4). Combined residues from the FL trial that included a fifth application to dill seed were 49.2 and 54.4 ppm, an obvious outlier and not in the same population as the remaining samples; these values were not included in the statistical calculation.

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Dill.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Fresh Dill	0.02	6	91, 79, 109, 94, 78, 84	89±12
	5.0	4	95, 86, 79, 80	85±7
	40.0	2	95, 98	97±2
	Total	**12**	**78-109**	**89±10**
Dill Seed	0.02	4	98, 86, 78, 90	88±8
	5.0	2	79, 80	80±1
	200	2	71, 76	74±4
	Total	**8**	**71-98**	**82±9**
BF 500-3				
Fresh Dill	0.02	6	85, 71, 115, 97, 98, 88	92±15
	5.0	4	94, 91, 80, 80	86±7
	40.0	2	93, 92	93±1
	Total	**12**	**71-115**	**90±11**
Dill Seed	0.02	4	67, 70, 87, 93	79±13
	5.0	2	72, 72	72
	200	2	71, 77	74±4
	Total	**8**	**67-93**	**76±9**

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (days)	Interval of Demonstrated Storage Stability (months)
Fresh Dill	<-10	171	19-25 [1]
Dill Seed		147	

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Dill Field Trials with Pyraclostrobin.

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Residues (ppm)		
						Pyraclostrobin	BF 500-3	Combined
Citra, FL 2003 FL54	3	Bouquet	0.81	Fresh Dill	0	18.96, 17.92	0.575, 0.562	19.54, 18.48
			1.0	Dill Seed	0	47.2, 52.6	2.03, 1.81	49.2, 54.4
Salinas, CA 2003 CA124	10	Bouquet	0.82	Fresh Dill	0	5.60, 8.85	0.141, 0.193	5.74, 9.04
			0.80	Dill Seed	0	19.2, 21.5	1.02, 1.05	20.2, 22.6
Moxee, CA 2003 WA17	11	Island Mammoth	0.82	Fresh Dill	0	9.99, 10.5	0.280, 0.30	10.27, 10.8
			0.83	Dill Seed	0	17.4, 17.9	0.613, 0.651	18.0, 18.6
Salisbury, MD 2003 MD23	2	Superdukat	0.81	Fresh Dill	0	3.84, 5.66	0.144, 0.190	3.98, 5.85
			0.81	Dill Seed	0	3.34, 3.84	0.251, 0.281	3.6, 4.1

TABLE C.4. Summary of Combined Residue Data from Dill Field Trials with Pyraclostrobin.									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Fresh Dill	0.81-0.82	0	8	3.98	19.54	19.01	9.66	10.46	5.79
Dill Seed	0.80-0.83	0	6	3.60	22.60	21.20	18.30	14.45	8.34

D. CONCLUSION

The dill field trial data are adequate and support the use of pyraclostrobin (BAS 500 02F) as four broadcast foliar sprays at ~0.20 lb ai/A/application during crop development for a total seasonal rate of ~0.80 lb ai/A. The data support a minimum RTI of 6 days and a 0-day PHI.

E. REFERENCES

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From: L. Cheng
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F. DOCUMENT TRACKING

RDI: G. Otakie 10/25/07; S. Hummel 10/31/07
Petition Number: 6E7165
DP#: 336189
PC Code: 099100

Template Version June 2005

Pyraclostrobin/BAS 500 F/PC Code 099100/IR-4
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
Crop Field Trial - Chives

Primary Evaluator	Gary Otakie, Chemist HED/RRB4 (7509P) Gary Otakie	Date: 10/25/07
Approved by	Susan V. Hummel, Branch Senior Scientist HED/RRB4 (7509P) Susan V. Hummel	Date: 10/31/07

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47014802. Carpenter, D.H. (2006) BAS 516: Magnitude of the Residue on Chives. Lab Project Number: 08793.03-BAR50. Unpublished study prepared by IR-4. 173 pages.

EXECUTIVE SUMMARY:

IR-4 has submitted field trial data for pyraclostrobin on chives. Four field trials were conducted in NAFTA Growing Zones 2 (MD, 1 trial), 5 (OH, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to chives as four directed foliar sprays at 0.20-0.21 lb ai/A/application for a total seasonal rate of 0.80-0.83 lb ai/A. Applications were made beginning when chive plants were at the vegetative stage and repeated on a 6- to 8-day retreatment interval using ground equipment (24-50 gal/A of spray volume) and did not include the use of a spray adjuvant. Applications included a tank mixture with another active ingredient (boscalid, formulated as BAS 510 UCF); only the residue data from treatments with pyraclostrobin are reported in this Data Evaluation Record.

Single control and duplicate treated samples of fresh chives were harvested immediately from each trial site following the last treatment (0 DAT). Samples were stored frozen for up to 115 days prior to analysis, an interval supported by available storage stability data.

Samples of harvested chives were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. The LOQ and LOD for fresh chives were statistically calculated as 0.029 ppm and 0.01 ppm for pyraclostrobin, and as 0.02 ppm and 0.007 ppm, respectively, for BF 500-3.

The results show that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.81-0.83 lb ai/A, combined residues were 0.7-8.8 ppm in/on 8 samples of fresh chives harvested immediately following the last treatment (0 DAT). The average combined residues in/on treated samples were 5.8 ppm.

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the chive field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 336189.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*. IR-4 has submitted field trial data in support label amendment for Pristine® Fungicide (EPA Reg. No.7969-199) to incorporate new uses on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs. Pristine® Fungicide is a WDG formulation containing multiple active ingredients of pyraclostrobin (12.8%) and boscalid (25.2%). The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

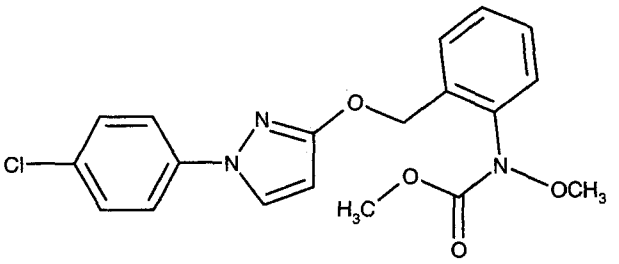
TABLE A.1. Pyraclostrobin Nomenclature.	
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	12.8% WDG (Pristine® Fungicide; EPA Reg. No. 7969-199, which also contains 25.2% of boscalid)

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.

Parameter	Value	References [1]	
		Laboratory Project Number	MRID
Melting point/range	63.7-65.2 °C	PCP03796: 1996/10327	45118213
pH	Not reported		
Density	1.285 g/cm^3 at 20°C	PCF01847: 1998/10768	45118212
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	PCP03797: 1996/10939 PCP04015: 1997/10693	45118233 45118234
Solvent solubility	Solvent — Solubility (mg/L) acetone ≥ 160 methanol 11 2-propanol 3.1 ethyl acetate ≥ 160 acetonitrile ≥ 76 dichloromethane ≥ 110 toluene ≥ 100 n-heptane 0.36 1-octanol 2.4 olive oil 2.9 DMF ≥ 62	PCP04037: 1996/10954	45118228
Vapor pressure	2.6 x 10^{-10} hPa at 20°C 6.4 x 10^{-10} hPa at 25°C	PCF01721: 1997/10646	45118214
Dissociation constant, pK_a	Does not dissociate in water.		
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	PCP03883: 1996/10383	45118215
UV/visible absorption spectrum	λ_{max} = 275 nm	PCP03799: 1996/10955	47220801

[1] Product Chemistry data were reviewed by the Registration Division under DP Barcode Numbers D269848 and D274191 (memo from S. Malak dated 03/May/2001; 20 pages).

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/g)
Salisbury, MD 2003	Loamy Sand	1.1	6.6	2.59
Willard, OH 2003	Sandy Loam	41.87	6.3	Not reported
Salinas, CA 2003	Loamy Sand	1.4	7.4	7.9
Moxee WA 2003	Sandy Loam	0.96	6.3	Not reported

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Salisbury, MD 2003	BAS 500 02F	Four broadcast foliar applications to mature leaves	24	0.20	6-8	0.81	None
Willard, OH 2003	BAS 500 02F	Four broadcast foliar applications during vegetation	27, 29	0.20-0.21	6-8	0.83	None
Salinas, CA 2003	BAS 500 02F	Four broadcast foliar applications during vegetation	50, 53	0.20-0.21	6-7	0.81	None
Moxee WA 2003	BAS 500 02F	Four broadcast foliar applications during vegetation	29, 28	0.20-0.21	7-8	0.82	None

[1] RTI = Retreatment Interval.

TABLE B.1.3. Trial Numbers and Geographical Locations.			
NAFTA Growing Zones	Chives		
	Submitted	Requested [1]	
		Canada	US
1			
2	1		
3			
4			
5	1		
6			
7			
8			
9			
10	1		
11	1		
12			
Total	4		3

[1] OPPTS 860.1500 requires three field trials but does not specify the geographic locations of the required residue field trials for chives.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (<2 lb) of mature chives were collected from each trial plot at 0 DAT. Fresh samples were stored frozen within 2.5 hours of collection and shipped frozen 10-60 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and were stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of fresh chives were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500-3 are expressed as pyraclostrobin equivalents. The LOQ and LOD for fresh chives were statistically calculated as 0.029 ppm and 0.01 ppm for pyraclostrobin, and as 0.02 ppm and 0.007 ppm, respectively, for BF 500-3.

The adequacy of Method D9908 was verified by fortifying control samples of chives with pyraclostrobin and BF 500-3 at 0.05 to 40.0 ppm.

C. RESULTS AND DISCUSSION

In a total of four field trials conducted during 2003, pyraclostrobin (BAS 500 02F) was applied to chives as four broadcast foliar sprays at 0.20-0.21 lb ai/A/application through vegetative development at RTIs of 6-8 days, for totals of 0.81-0.83 lb ai/A. All applications were made using ground equipment at 24-50 gal/A, and did not include the use of a spray adjuvant. Single control and duplicate treated samples of chives were harvested from each test at 0 DAT.

Chive samples were stored frozen for 115 days prior to analysis. Storage stability data are available indicating that both pyraclostrobin and BF 500-3 are stable in frozen storage for 19-25 months in representative plant matrices (DP# 269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on chives was adequately validated in conjunction with the field trials. Concurrent recoveries of pyraclostrobin averaged 86% with a standard deviation of 12%, and recovery of BF 500-3 averaged 81% with a standard deviation of 8% (see Table C.1). Apparent residues of pyraclostrobin were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results indicate that following four applications of pyraclostrobin (BAS 500 02F) totaling 0.81-0.83 lb ai/A, the combined residues were 0.7-8.8 ppm in/on 8 samples of chives harvested at 0 DAT (see Table C.3). Average combined residues were 5.8 ppm, and the HAFT was 7.8 ppm (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Chives.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Chives	0.02	5	95, 91, 44[1], 80, 115, 90	94 ± 13
	5.0	4	82, 80, 74, 77	78 ± 4
	50.0	2	85, 76	81 ± 6
	Total	**11**	**74-115**	**86 ± 12**
BF 500-3				
Chives	0.02	6	99, 88, 82, 77, 88, 75	85 ±9
	5.0	4	77, 75, 72, 78	76 ± 3
	50.0	2	87, 74	81 ± 9
	Total	**12**	**72-99**	**81 ± 8**

TABLE C.2. Summary of Storage Conditions.			
Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (days)	Interval of Demonstrated Storage Stability (months)
Chives	<-10	115	19-25 [1]

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Chive Field Trials with Pyraclostrobin.								
Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Residues (ppm)		
						Pyraclostrobin	BF 500-3	Combined
Salisbury, MD 2003	2	Staro	0.81	Chives	0	6.6, 6.7	0.25, 0.26	6.85, 6.96
Willard, OH 2003	5	Fancy	0.83	Chives	0	8.7, 6.8	0.09, 0.07	8.79, 6.87
Salinas, CA 2003	10	Purly	0.81	Chives	0	7.8, 6.9	0.17, 0.15	7.97, 7.05
Moxee WA 2003	11	Staro	0.82	Chives	0	0.69, 1.1	0.03, 0.04	0.71, 1.10

TABLE C.4. Summary of Combined Residue Data from Chive Field Trials with Pyraclostrobin.									
Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Chives	0.81-0.83	0	8	0.7	8.8	7.8	6.9	5.8	3.1

D. CONCLUSION

The chive field trial data are adequate and support the use of pyraclostrobin (BAS 500 02F) as four broadcast foliar sprays at ~0.20 lb ai/A/application during crop development for a total seasonal rate of ~0.80 lb ai/A. The data support a minimum RTI of 6 days and a 0-day PHI.

E. REFERENCES

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data.
From: L. Cheng
To: C. Giles-Parker/J. Bazuin
Dated: 11/28/01
MRIDs: 45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: G. Otakie 10/25/07; S. Hummel 10/31/07
Petition Number: 6E7165
DP#: 336189
PC Code: 099100

Template Version June 2005

Pyraclostrobin/BAS 500 F/PC Code 099100/IR-4
DACO 7.4.1/7.4.2/OPPTS 860.1500/OECD IIA 6.3.1, 6.3.2, 6.3.3 and IIIA 8.3.1, 8.3.2, 8.3.3
DACO 7.4.5/OPPTS 860.1520/OECD IIA 6.5.4 and IIIA 8.5
Crop Field Trial – Fresh Basil; Processed Food and Feed – Dried Basil

Primary Evaluator	Gary Otakie, Chemist HED/RRB4 (7509P) Gary Otakie	Date: 10/25/07
Approved by	Susan V. Hummel, Branch Senior Scientist HED/RRB4 (7509P) Susan V. Hummel	Date: 10/31/07

In the absence of signatures, this document is considered to be a draft with deliberative material for internal use only.

This DER was originally prepared under contract by Dynamac Corporation (1910 Sedwick Road, Building 100, Suite B; Durham, NC 27713; submitted 7/31/2007). The DER has been reviewed by the Health Effects Division (HED) and revised to reflect current Office of Pesticide Programs (OPP) policies.

STUDY REPORT:

47014803. Carpenter, D.H. (2006) BAS 516: Magnitude of the Residue on Basil. Lab Project Number: 08792.03-BAR04. Unpublished study prepared by IR-4. 203 pages.

EXECUTIVE SUMMARY:

IR-4 has submitted field trial data for pyraclostrobin on basil. Four field trials were conducted in NAFTA Growing Zones 1 (NY, 1 trial), 3 (FL, 1 trial), 10 (CA, 1 trial), and 11 (WA, 1 trial) during the 2003 growing season. The test formulation used in all trials was BAS 500 02F, which was identified as either Headline® Fungicide (EPA Reg. No. 7969-186, 2.0 lb/gal EC) or Cabrio® Fungicide (EPA Reg. No. 7969-187, 20% WDG). BAS 500 02F was applied to basil as four directed foliar sprays at 0.20-0.21 lb ai/A/application for a total seasonal rate of 0.80-0.83 lb ai/A. Applications were made beginning when basil plants were at the vegetative/flowering stage and repeated on a 6- to 8-day retreatment interval using ground equipment (28-54 gal/A of spray volume) and did not include the use of a spray adjuvant. Applications included a tank mixture with another active ingredient (boscalid, formulated as BAS 510 UCF); only the residue data from treatments with pyraclostrobin are reported in this Data Evaluation Record.

Single control and duplicate treated samples of fresh basil were harvested from each test site at 0 and 3 days after treatment (DAT). Additional fresh basil samples were collected at 0 DAT and then dried according to simulated commercial practices in order to generate residue data for dried basil. Samples were stored frozen for up to 172 days prior to analysis, an interval supported by available storage stability data.

Samples of fresh and dried basil were analyzed for residues of pyraclostrobin and its metabolite BF 500-3 using Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Method D9908 is adequate for data collection based on acceptable concurrent method recoveries. The LOD and LOQ for fresh basil were statistically calculated as 0.008 ppm and 0.024 ppm for pyraclostrobin, and as 0.003 ppm and 0.010 ppm, respectively, for BF 500-3.

The results show that following four spray applications of pyraclostrobin (BAS 500 02F) totaling 0.80-0.83 lb ai/A, combined residues were 7.2-21.1 ppm in/on 8 samples of fresh basil harvested at 0 DAT, 1.3-7.5 ppm in/on 8 samples of fresh basil harvested at 3-4 DAT, and 40.1-80.6 ppm in/on dried basil harvested at 0 DAT. Average combined residues were 10.9 ppm in fresh basil harvested at 0 DAT, 4.8 ppm in fresh basil harvested at 3-4 DAT, and 67.5 ppm in dried basil harvested at 0 DAT. The processing of fresh basil to dried basil resulted in an increase of total residues with a processing factor range of 4.6-9.0x (average factor of 6.5x).

STUDY/WAIVER ACCEPTABILITY/DEFICIENCIES/CLARIFICATIONS:

Under the conditions and parameters used in the study, the basil field trial data are classified as scientifically acceptable. The acceptability of this study for regulatory purposes is addressed in the forthcoming U.S. EPA Residue Chemistry Summary Document, DP# 336189.

COMPLIANCE:

Signed and dated Good Laboratory Practice (GLP), Quality Assurance and Data Confidentiality statements were provided. No deviations from regulatory requirements were reported which would have an adverse impact on the validity of the study.

A. BACKGROUND INFORMATION

Pyraclostrobin belongs to the strobilurin class of fungicides. Strobilurins are synthetic analogs of a natural antifungal substance which inhibits spore germination and inhibits mycelial growth and sporulation of the fungus on the leaf surface. The fungicide is currently registered to BASF Corporation (BASF) for use on a variety of field, vegetable, fruit and nut crops. Permanent tolerances are established [40 CFR §180.582(a)(1)] for the combined residues of pyraclostrobin and its desmethoxy metabolite (BF 500-3), expressed as parent, in/on numerous plant commodities at levels ranging from 0.02 ppm in/on wheat grain to 29 ppm in/on leafy vegetables, except *Brassica*. IR-4 has submitted field trial data in support label amendment for Pristine® Fungicide (EPA Reg. No.7969-199) to incorporate new uses on avocado, black sapote, canistel, mamey sapote, mango, papaya, sapodilla, star apple, and fresh herbs. Pristine® Fungicide is a WDG formulation containing multiple active ingredients of pyraclostrobin (12.8%) and boscalid (25.2%). The chemical structure and nomenclature of pyraclostrobin are presented in Table A.1. The physicochemical properties of the technical grade of pyraclostrobin are presented in Table A.2.

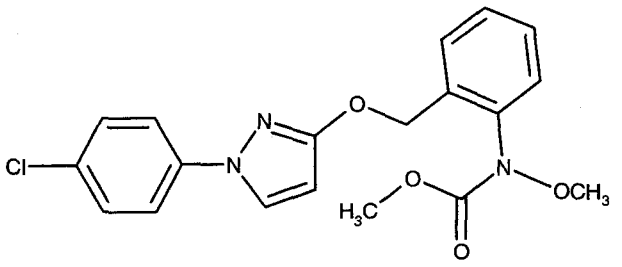
TABLE A.1. Pyraclostrobin Nomenclature.	
Compound	
Common name	Pyraclostrobin
Company experimental name	BAS 500 F
IUPAC name	methyl *N*-{2-[1-(4-chlorophenyl)-1*H*-pyrazol-3-yloxymethyl]phenyl}(*N*-methoxy) carbamate
CAS name	methyl [2-[[[1-(4-chlorophenyl)-1*H*-pyrazol-3-yl]oxy]methyl]phenyl]methoxycarbamate
CAS registry number	175013-18-0
End-use product (EP)	12.8% WDG (Pristine® Fungicide; EPA Reg. No. 7969-199, which also contains 25.2% of boscalid)

TABLE A.2. Physicochemical Properties of Technical Grade Pyraclostrobin.		
Parameter	Value	References [1]
Melting point/range	63.7-65.2EC	D269848 & D274191
pH	Not reported	D269848 & D274191
Density	1.285 g/cm^3 at 20EC	D269848 & D274191
Water solubility at 20°C	2.41 mg/L (deionized water) 1.9 mg/L (pH 7) 2.3 mg/L (pH 4) 1.9 mg/L (pH 9)	D269848 & D274191
Solvent solubility	acetone (∃160 mg/L); methanol (11 mg/L); 2-propanol (3.1 mg/L); ethyl acetate (∃160 mg/L); acetonitrile (∃76 mg/L); dichloromethane (∃110 mg/L); toluene (∃100 mg/L); n-heptane (0.36 mg/L); 1-octanol (2.4 mg/L); olive oil (2.9 mg/L); DMF (∃62 mg/L).	D269848 & D274191
Vapor pressure	2.6 x 10^{-10} hPa at 20EC 6.4 x 10^{-10} hPa at 25°C	D269848 & D274191
Dissociation constant, pK_a	Does not dissociate in water.	D269848 & D274191
Octanol/water partition coefficient, Log(K_{OW}) at room temperature	3.80 at pH 6.2 4.18 at pH 6.5	D269848 & D274191
UV/visible absorption spectrum	λ_{max} = 275 nm	D269848

[1] Product Chemistry data were reviewed by the Registration Division (DP# 269848 and D274191, 5/3/01, 5/15/01, and 6/7/01, S. Malak).

B. EXPERIMENTAL DESIGN

B.1. Study Site Information

TABLE B.1.1. Trial Site Conditions.

Trial Identification (City, State/Province; Year)	Soil characteristics			
	Type	% OM	pH	CEC (meq/g)
Freesville, NY 2003	Silt Loam	6.35	6.75	Not reported
Citra, FL 2003	Coarse Sand	1.92-2.04	5.6	Not reported
Salina, CA 2003	Loamy Sand	1.4	7.4	7.9
Moxee, WA 2003	Sandy Loam	0.96	6.3	Not reported

Weather conditions were considered normal for each test site during the study period. Temperature and rainfall were within the historical averages. Irrigation was used to supplement precipitation as needed. There were no meteorological abnormalities that occurred during the conduct of the study. Information on maintenance pesticides and fertilizers was also provided for each site.

TABLE B.1.2. Study Use Pattern for Pyraclostrobin.

Location (City, State/Province; Year) Trial ID	End-use Product	Application Information					Tank Mix/ Adjuvants
		Method; Timing	Volume (GPA)	Single Rate (lb ai/A)	RTI [1] (days)	Total Rate (lb ai/A)	
Freeville, NY 2003 NY17	BAS 500 02F	Four broadcast foliar applications during flowering	31-32	0.20-0.21	6-8	0.83	None
Citra, FL 2003 FL55	BAS 500 02F	Four broadcast foliar applications from bloom to vegetation	30-31	0.20-0.21	7	0.82	None
Salina, CA 2003 CA 125	BAS 500 02F	Four broadcast foliar applications during vegetation	46-54	0.20	6-8	0.80	None
Moxee, WA 2003 WA18	BAS 500 02F	Four broadcast foliar applications during bloom	28-29	0.20-0.21	6-7	0.82	None

[1] RTI = Retreatment Interval.

113

TABLE B.1.3. Trial Numbers and Geographical Locations.

NAFTA Growing Zones	Basil		
	Submitted	Requested [1]	
		Canada	US
1	1		
2			
3	1		
4			
5			
6			
7			
8			
9			
10	1		
11	1		
12			
Total	4		3

[1] OPPTS 860.1500 requires three field trials but does not specify the required geographic locations of residue field trials for basil.

B.2. Sample Handling and Preparation

Single control and duplicate treated samples (<2 lbs) of fresh basil were collected from each trial plot at 0 and 3 DAT. Additional samples (<0.5 lb) were collected at 0 DAT and dried according to local commercial practice. All samples were stored frozen within 1.5 hours of collection and then shipped frozen 7-33 days after harvest via ACDS Freezer truck to the analytical laboratory, BASF Agro Research (RTP, NC). Samples were received frozen from the field and stored in a freezer (< -10 °C) prior to homogenization and analysis.

B.3. Analytical Methodology

Samples of fresh and dried basil were analyzed for residues of pyraclostrobin and the metabolite BF 500-3 using BASF Analytical Method D9908 entitled "Method for Determining BAS 500F, BF 500-3, and BAS 510F Residues in Plant Matrices using LC/MS/MS". Briefly, residues were extracted by shaking with methanol:water:2 N HCl (70:25:5; v:v:v) and centrifuged. Residues were then partitioned with cyclohexane, concentrated to dryness, and re-dissolved in buffered methanol:water (80:20, v:v). The final chromatographic analysis of residues was determined by LC/MS/MS. Total residues of pyraclostrobin and BF 500-3 are expressed as pyraclostrobin equivalents. The LOD and LOQ for fresh basil were statistically calculated as 0.008 ppm and 0.024 ppm for pyraclostrobin, and as 0.003 ppm and 0.010 ppm, respectively, for BF 500-3.

C. RESULTS AND DISCUSSION

In a total of four field trials conducted during 2003, pyraclostrobin was applied to basil as four broadcast foliar sprays at 0.20-0.21 lb ai/A/application through flowering and vegetation stages with RTIs of 6-8 days, for totals of 0.80-0.83 lb ai/A. All applications were made using ground equipment at 28-54 gal/A, and did not include the use of a spray adjuvant. Single control and duplicate treated samples of fresh basil were harvested from each test at 0 and 3 DAT.

114

Additional samples were harvested at 0 DAT and then dried according to simulated commercial practices.

Basil samples were stored frozen for 172 days prior to analysis. Storage stability data are available indicating that both pyraclostrobin and BF 500-3 are stable in frozen storage for 19-25 months in representative plant matrices (DP# 269668, L. Cheung, 11/28/01).

The LC/MS/MS method (BASF Method D9908) for determining residues of pyraclostrobin and BF 500-3 in/on basil was adequately validated in conjunction with the field trial. Concurrent recoveries of pyraclostrobin averaged 92% with a standard deviation of 15% in fresh basil and 85% with a standard deviation of 9% in dried basil. Average recovery of BF 500-3 in fresh basil was 94% with a standard deviation of 7% and in dried basil, average recovery was 83% with a standard deviation of 7% (see Table C.1). Apparent residues were <LOQ ppm in/on all control samples. Adequate sample calculations and example chromatograms were provided. Concurrent recoveries bracketed residues found in treated samples.

The results show that following four applications of pyraclostrobin totaling 0.80-0.83 lb ai/A, the combined residues were 7.2-21.1 ppm in/on 8 samples of fresh basil harvested at 0 DAT, 1.3-7.5 ppm in/on 8 samples of fresh basil harvested at 3-4 DAT, and 40.1-80.6 ppm in dried basil harvested at 0 DAT. The average processing factor for dried basil is 6.5x (see Table C.3). Average combined residues were 10.9 ppm in fresh basil harvested at 0 DAT, 4.8 ppm in fresh basil harvested at 3-4 DAT, and 67.5 ppm in dried basil harvested at 0 DAT (see Table C.4).

Common cultural practices were used to maintain plants, and the weather conditions and the maintenance chemicals and fertilizer used in the study did not have a notable impact on the residue data.

TABLE C.1. Summary of Concurrent Recoveries of Pyraclostrobin from Basil.

Matrix	Spike level (ppm)	Sample size (n)	Recoveries (%)	Mean, ± standard deviation (%)
Pyraclostrobin				
Fresh Basil	0.05	6	87, 103, 114, 104, 106, 119	106±11
	5.0	6	84, 78, 76, 76, 73, 87	79±5
	50.0	2	98, 82	90±11
	Total	**14**	**73-119**	**92±15**
Dried Basil	0.05	2	85, 101	93±11
	50.0	2	80, 80	80
	200	2	76, 90	8310±
	Total	**6**	**76-101**	**85±9**
BF 500-3				
Fresh Basil	0.05	6	94, 87, 96, 84, 85, 88	89±5
	5.0	6	86, 83, 74, 75, 74, 89	80±7
	50.0	2	88, 77	83±8
	Total	**14**	**74-94**	**84±7**
Dried Basil	0.05	2	80, 94	87±10
	50.0	2	85, 78	82±5
	200	2	74, 85	80±8
	Total	**6**	**74-94**	**83±7**

TABLE C.2. Summary of Storage Conditions.

Matrix	Storage Temperature (°C)	Actual Storage Duration, Days (days)	Interval of Demonstrated Storage Stability (months)
Fresh Basil	<-10	172	19-25 [1]
Dried Basil		161	

[1] DP# 269668, L. Cheung, 11/28/01.

TABLE C.3. Residue Data from Basil Field Trials with Pyraclostrobin.

Trial ID (City, State; Year)	Zone	Variety	Total Rate (lb ai/A)	Commodity	PHI (days)	Residues (ppm)		
						Pyraclostrobin	BF 500-3	Combined
Freeville, NY 2003 NY17	1	Italian Large Leaf	0.83	Fresh Basil	0	8.42, 7.12	0.095, 0.087	8.52, 7.21
					3	3.93, 3.91	0.116, 0.124	4.05, 4.03
				Dried Basil	0	39.72	0.385	40.10 [5.1x] [1]
Citra, FL 2003 FL55	3	Degenova	0.82	Fresh Basil	0	8.98, 12.7	0.179, 0.271	9.16, 12.97
					4	7.11, 5.44	0.303, 0.252	7.41, 5.69
				Dried Basil	0	78.8	1.77	80.57 [7.3x] [1]
Salina, CA 2003 CA 125	10	Genovese	0.80	Fresh Basil	0	20.8, 10.9	0.279, 0.190	21.07, 11.09
					4	1.23, 1.20	0.065, 0.071	1.30, 1.27
				Dried Basil	0	72.68	1.069	73.75 [4.6x] [1]
Moxee, WA 2003 WA18	11	Italian Large Leaf	0.82	Fresh Basil	0	7.94, 8.54	0.136, 0.157	8.08, 8.70
					3	7.02, 7.23	0.284, 0.269	7.30, 7.50
				Dried Basil	0	74.4	1.339	75.74 [9.0x] [1]

[1] Values in bracket are the processing factors calculated from drying of fresh basil. The average residues of two fresh basil samples were used for calculation.

116

TABLE C.4. Summary of Combined Residue Data from Basil Field Trials with Pyraclostrobin.

Commodity	Total Applic. Rate (lb ai/A)	PHI (days)	Residue Levels (ppm)						
			n	Min.	Max.	HAFT	Median (STMdR)	Mean (STMR)	Std. Dev.
Fresh Basil	0.80-0.83	0	8	7.2	21.1	16.1	8.9	10.9	4.5
		3-4	8	1.3	7.5	7.4	4.9	4.8	2.6
Dried Basil		0	4	40.1	80.6	80.6	74.7	67.5	18.5

D. CONCLUSION

The field trial data are adequate and support the use of pyraclostrobin on basil for four broadcast foliar sprays at ~0.20 lb ai/A/application during crop development, for a total seasonal rate of ~0.80 lb ai/A. The data support a minimum RTI of 6 days, a 0- or 3-day PHI for fresh basil and a 0-day PHI for dried basil. The average processing factor for dried basil is 6.5x.

E. REFERENCES

DP#s: 269668, 272771, 272789, 274095, 274192, 274471, 274957, 275843, and 278429
Subject: PP#0F06139. Pyraclostrobin on Various Crops: Bananas (import), Barley, Berries, Bulb Vegetables, Citrus Fruits, Cucurbit Vegetables, Dried Shelled Pea & Bean (except Soybean), Fruiting Vegetables, Grapes, Grass, Peanut, Pistachio, Root Vegetables (except Sugar Beet), Rye, Snap Beans, Stone Fruits, Strawberry, Sugar Beet, Tree Nuts, Tuberous and Corm Vegetables, and Wheat. Review of Analytical Methods and Residue Data
From: L. Cheng
To: C. Giles-Parker/J. Bazuin
Dated: 11/28/01
MRIDs: 45118428-451184-37, 45118501-45118512, 45118514-45118537, 45118601-45118625, 45160501, 45272801, 45274901, 45321101, 45367501, 45399401, and 45429901

F. DOCUMENT TRACKING

RDI: G. Otakie 10/25/07; S. Hummel 10/31/07
Petition Number: 6E7165
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117

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